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‘A text message based weight management intervention’

Eleanor L. Donaldson

Student No. 0816798

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A text message based weight management intervention for overweight adults.

E.L. DONALDSON

Leicestershire Nutrition & Dietetic Service, Charnwood Mill, Sileby Rd, Barrow Upon Soar, Leicester, LE12 8LR

Purpose: This study aimed to determine whether a text message based intervention helped participants maintain or lose weight following completion of a weight loss programme. Low fat diet, regular exercise, breakfast consumption, goal setting and self monitoring are behaviours of weight losers and maintainers (Wing & Hill, 2001). Weight management interventions can be enhanced using mobile telephone technology to deliver support in real time, real world settings (Heron & Smyth, 2010)

Methods: In this controlled study, overweight adults completing a weight management programme participated in an additional 12-week text message based intervention ('LEAP Beep'). Participants ($n=17$, 7 males; 10 females; mean age 58.3 ± 12.1 years) were allocated daily targets for steps, fruit, vegetable and breakfast consumption. Twice weekly, participants 'texted' with progress and received practitioner feedback. Pre and post intervention body mass, waist circumference, Body Mass Index (BMI), quality of life (QOL), anxiety and depression measurements were collected and compared retrospectively to a control group ($n=17$; 4 males, 13 females; mean age 59.1 ± 9.5 years) receiving optional weight checks only (standard care). Paired t tests and Wilcoxon signed ranks tests evaluated differences between pre and post intervention variables.

Results: Compared to the control, intervention group body mass, waist circumference and BMI reduced significantly ($p=0.006$; $p=0.0005$; $p=0.03$). QOL and depression scores improved, but not significantly ($p=0.134$; $p=0.228$). No difference was found between group anxiety scores (table 1.) Satisfaction surveys showed 100% ($n=14$) of participants strongly agreed they were satisfied with the overall programme

Table 1. Difference in health variables between intervention and control groups

Variable	Intervention group actual change	Control group actual change	Between group difference	Difference between groups (p value)
Body mass (kg)	-1.6	+0.7	2.3	0.006
Waist circumference (cm)	-2.2	+1.5	3.7	0.0005
BMI (kg/m^2)	-0.6	+0.7	1.5	0.03
QOL (points)	-6.8	+1	7.8	0.134
Depression (points)	-0.2	+0.2	-0.4	0.228
Anxiety (points)	-0.1	-0.1	0	-

Conclusions: 'LEAP Beep' resulted in weight and waist circumference losses, improved quality of life parameters and was highly acceptable to participants. Text messaging is a cheap, portable, convenient and innovative contact medium that promotes goal setting, self monitoring and facilitates information exchange with patients. Text messaging inclusive of practitioner feedback opens up increasing possibilities for practitioner to patient support and helps maintain a positive weight outcome following initial weight loss. Further improvements to automation whilst maintaining individual support are necessary to ease practitioner burden.

Key words: Obesity; Mobile telephone; Self monitoring; Weight maintenance; Quality of life

Declaration

This work is original and has not been submitted previously in support of a degree qualification or other course

Signed:

Printed: ELEANOR DONALDSON

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Chapter 1.0 Introduction

1.1 National Picture

The World Health Organisation [WHO] (2003) describes the problem of obesity as a "worldwide epidemic". In 2006, 24% of adults in England were classified as obese (NHS, 2008). The UK Government's Foresight report '*Tackling Obesities: Future Choices*' (2007) indicated that by 2050, 60% of men, 50% of women and approximately 25% of children under 16 could be classified as obese.

Obesity is the result of a positive energy imbalance over a period of time such that more calories are consumed than are expended. Obesity increases the risk of a wide range of diseases including coronary heart disease, type 2 diabetes, hypertension and some types of cancers (Department of Health, 2004).

1.2 Local context

In Leicestershire and Rutland approximately 124,600 adults are obese (East Midlands Public Health Observatory, 2006). Levels of obesity are predicted to continue rising and this will have an impact on the population's disease burden. Rates of adult obesity are higher in the East Midlands (25.6%) than the national average (23.6%) and this has been a consistent trend in recent years (Association of Public Health Observatories, 2009).

1.3 Behavioural Strategies

High costs for obesity related health care mean researchers and clinicians are continually searching for cost effective and successful treatments for weight loss and maintenance (Berkel, Poston, Reeves & Foreyt, 2005). However, the role of patient behaviour within this balance is coming under increasing focus.

Taking into consideration the highly variable psychological, biological and environmental differences within the obese population; one single treatment alone

could never be effective (Clark, Guise and Niaura, 1995). Any treatment will be useful to some people, but no treatment will work for all; more focus should be given to the pairing of patients' needs and treatment features (Brownell & Wadden, 1992). National Institute of Health and Clinical Excellence [NICE] Obesity Guidelines (NICE, 2006) emphasise the need for interventions to include dietary, physical activity and behavioural strategies for successful outcomes. This treatment combination is known widely as 'lifestyle modification' (Fabricatore & Wadden, 2003).

Behavioural strategies to support weight loss and maintenance can include:

- Self-monitoring of behaviour and progress
- Goal setting
- Problem solving
- Relapse prevention
- Strategies for dealing with weight regain

(NICE, 2006)

A necessary pre-condition for behaviour change is the awareness of the problem and a personal desire to change (Dionne & Yeudall, 2005). Practitioners should empower patients with skills such as self monitoring and goal setting that can be utilised throughout their lives for long term health change.

1.4 Weight Maintenance and Regain

It is particularly challenging to prevent weight regain following weight loss. The intrinsic challenge of losing weight and preventing weight regain, leads many to seek assistance (e.g., a counselling programme, community support group or self-help book) to help initiate or sustain the behaviour modifications necessary to lose weight.

These self help methods rely on competency in behavioural management skills (VanWormer, French, Pereira & Welsh, 2008).

To highlight this point, Wing et al. (2006) studied a cohort of 314 overweight and obese Americans over 18 months. Following successful weight loss, participants were randomised to one of three intervention groups;

1. Self directed care including quarterly newsletter;
2. Face to face consultations with a health professional (self regulation);
3. An internet based programme (self regulation).

Wing et al. (2006) found that with only self directed care (minimal intervention), 72% of the group regained more than 2.3 kg over an 18 month period. Of the other two interventions, 55% of the internet based programme and 46% of the face to face intervention group respectively regained 2.3 kg or more. The study is strengthened because only successful dieters (loss of ≥ 19 kg at baseline) were recruited and a high rate (93%) of participants completed the 18 month reviews (financial incentives were given). Wing et al. (2006) concluded that the two self regulation interventions were more effective than self direction for weight maintenance.

1.4.1 Successful Behaviours of Weight Maintenance

As practitioners, we need to better understand the factors associated with weight loss maintenance and how they can be promoted to prolong a healthier body weight for as long as a time period as possible (Elfhag & Rossner, 2004).

An examination of behavioural modifications to support weight maintenance should begin with the United States based National Weight Control Registry (NWCR) (Wing & Hill, 2001). Established in 1994, the Registry consists of over 4800 individuals who

have been successful in long-term weight loss maintenance. It is the largest prospective investigation of long-term successful weight loss maintenance. Enrolment onto the registry is dependent on individuals having successfully lost ≥ 30 lbs and maintained that weight loss for a minimum of 1 year. Questionnaires and annual review surveys examine behavioural and psychological characteristics of weight maintainers and their strategies to maintain weight losses. The NWCR found common health behaviours between weight losers and found that weight loss and maintenance was supported by:

- Consuming a diet low in fat;
- Eating breakfast almost every day;
- Frequent self monitoring of body weight and food intake;
- High levels of regular physical activity (approximately 1 hour/day)

(Wing & Hill, 2001)

However, NWCR registry entry and subsequent follow up data are based entirely on self reported measurements. Obesity-related mis-reporting bias is well accepted; obese people tend to underestimate their dietary intake and over estimate their physical activity (Lissner, Heitmann & Bengtsson, 2000).

Characteristics of registry members involved in the research reveal a poor representation from ethnic minorities, males and a range of educational statuses; 94.7% of members are white; 75.1% of members are female; 31.5% are graduate or professional status (Butryn, Phelan, Hill & Wing, 2007). Although this data is unrepresentative of the entire population and has limited extrapolation potential, it does give insight into what has been a successful strategy for a large number of people.

Wing and Hill, (2001) and Elfhag and Rossner (2004) discuss that of the many positive factors associated with successful weight outcomes, three lifestyle behaviours (along with regular self monitoring) can be agreed upon as standing out:

- Physically active lifestyle
- Breakfast eating
- Less dietary fat, more healthy foods

1.4.1.1 *Physically active lifestyle*

Recommendations

Adults should undertake at least 30 minutes of at least moderate-intensity physical activity on 5 or more days a week. To prevent obesity, 45–60 minutes may be needed. In those that have lost weight 60–90 minutes may be necessary to avoid regaining weight (NICE, 2006).

Current UK data

The annual Health Survey of England (HSE) monitors UK health. Each year approximately 16,000 adults and 4,000 children are interviewed and lifestyle data are collected (Department of Health, 2006). Figure 1. Shows data from the 2008 HSE (most recent available) shows that based on accelerometry, only 6% of males and 4% of females met the government's current recommendations for physical activity in the week of accelerometer wear, accumulated in bouts of at least 10 minutes (The Health and Social Care Information Centre, 2008).

Figure 1. Percentage of adults that meet UK physical activity recommendations. (The Health and Social Care Information Centre, 2008)

Advice to patients

Physical activity can be sought in different ways;

- Structured exercise programmes that encourage specific activities such as aerobics, swimming, jogging or football
- Incorporation of activity into daily living i.e. walking rather than using lifts or escalators - small changes everyday can make a substantial difference
- Reduction of sedentary behaviours such as sitting in front of the television, playing computer games, or using the computer (NICE, 2006)

1.4.1.2 *Breakfast consumption*

Recommendations

National obesity guidance lists 'eat breakfast' as one of the key components of a healthy balanced diet (NICE, 2006).

Advice to patients

Wyatt, Grunwald, Mosca, Klem, Wing and Hill (2001) found that 78% of people surveyed in the NWCR reported breakfast eating every day; this could be a factor in their success.

1.4.1.3 *Less dietary fat, more healthy foods*

Recommendations

Since a WHO report (2003) on 'Diet, Nutrition and the Prevention of Chronic Diseases', the United Kingdom Department of Health has recommended that the general public eat at least five portions of fruit and vegetables each day.

Current UK data

Data from the 2008 HSE shows the average UK daily fruit and vegetable consumption measured in portions per day, based on consumption the day before the interview (The Health and Social Care Information Centre, 2008) [Figure 2].

Figure 2. Fruit and vegetable consumption in UK adults. (The Health and Social Care Information Centre, 2008)

Portions are expressed in everyday units to make accurate consumption recall easier. Data collected showed that only 25% of men and 29% of women consumed the recommended five or more portions of fruit and vegetables daily (The Health and Social Care Information Centre, 2008).

Advice to patients

The fibre and water in foods increases volume and subsequently reduces energy density. In their whole state, fruits and vegetables are high in water and fibre and low in calories and energy density (National Centre for Chronic Disease Prevention & Health Promotion, 2005). Increased consumption of fruit and vegetables can offset high fat and calorie foods (Robinson 1999). Replacing highly energy dense foods with foods of lower energy density, can be a practical and effective weight management strategy (National Centre for Chronic Disease Prevention & Health Promotion, 2005).

Practitioners with the knowledge about factors predicting weight loss should harness these to develop and teach strategies for weight maintenance, tackling the increasing challenge of obesity compounded by ever decreasing service resources for its delivery (Elfhag & Rossner, 2004).

1.5 Self Monitoring

Self monitoring is a common behaviour of successful weight losers. Many dieters regain the weight they lose, therefore programmes to promote maintenance skills are vital (Wing, Tate, Gorin, Raynor & Fava, 2006; Wing & Hill, 2001).

A focus on self monitoring has been a considerable source of interest in obesity literature, many researchers and institutions consider it a key behavioural strategy in weight management (Berkel et al, 2005; NICE, 2006; Wing & Hill, 2001). The aim of self monitoring is to increase self awareness of specific behaviours and their relative

outcomes. This therefore acts as an early warning system should issues appear and can also be used to mark achievements (Yeager, Heim, Seiler & Lofton, 2008).

Early research into the behavioural effects of self-monitoring was undertaken by McFall. (Gottman & McFall, 1972 & McFall, 1970 as cited by Shay, 2008). His work was prompted by participants' awareness of data collection during a study and the subsequent reactive process that affected the behaviour under observation.

Self monitoring is an effective behavioural strategy; it leads to the recognition of excess weight and motivates change. Korotitsch and Nelson-Gray (1999) comment that self monitoring ultimately leads to a change in target behaviour; to control dietary intake and physical activity through simple observation.

In weight management and maintenance, some commonly used self monitoring methods are food and exercise diaries, regular self-weighing and pedometers (Yeager et al. 2008).

Dionne and Yeudall (2005) observed that many studies examining self monitoring and weight are correlational. It is therefore unclear whether frequent monitoring or the keeping of food diaries itself is directly linked to weight loss or whether "successful losers" are more likely to self monitor regardless. Consequently, self monitoring could be as much of a cause as an effect of weight management.

1.6 Text messaging

National obesity guidance recommends long-term follow up of patients for weight management support (NICE, 2006). However, the challenges faced when providing extended intervention include cost and adherence over long time periods (Walcott-

McQuigg, Chen, Davis, Stevenson, Choi & Wangsrikhun, 2002). Wing, (2000) suggested that alternative options requiring less direct face-to-face would be useful.

Increasingly hectic lifestyles mean that keeping written food and exercise diaries as a self monitoring tool is losing favour. Much quicker and convenient is to use relatively new technologies such as Short Message Service text messaging ('texting').

Health behaviour treatments can be enhanced beyond traditional research or clinical settings by using mobile technology to deliver interventions as people go about their daily lives. These interventions are sent to people during their everyday lives (i.e. in real time) in natural settings (i.e. real world) (Heron & Smyth, 2010). A review of 27 interventions using either palmtop computers or mobile phones to deliver mobile treatments for weight loss and other health behaviours found the interventions to be successfully delivered, acceptable to patients and efficacious.

In developed countries the extensive public uptake of new communication technologies—most notably the World Wide Web, wireless Personal Digital Assistants, and mobile (cellular) telephones can and should be harnessed for the benefit of health (Tufano & Karras, 2005).

Mobile phones offer the opportunity to develop successful behaviours of weight management such as self-monitoring, in particular by text messaging. Text messaging is a low cost, portable contact method that enables two way practitioner-to-patient communications. Utilising this method of 'remote support' can be an effective way to support patients in weight management. Giving personalised feedback on responses equips patients with a behavioural strategy to help sustain positive lifestyle changes (Patrick et al. 2009).

A MEDLINE review of the major commercial weight loss programmes in the United States found that patients can lose motivation when the discipline of a weight management intervention finishes. The review found attrition rates of up to 56% at 26 weeks for weight management groups (Tsai & Wadden, 2005).

Text messaging may be able to offer a solution to this problem of high attrition after a weight management course as well as providing a convenient feedback mechanism to support self monitoring.

Previous research has found the efficacy of using text messaging to support other health behaviours e.g.

- Adult smoking cessation (Obermayer, Riley, Asif & Jean Mary, 2004)
- Improved glycaemic control in teenage diabetics (Franklin, Waller, Pagliari & Greene, 2006)
- Physical activity (Hurling, Catt, De Boni, Fairley & Hurst et al. 2007)
- Asthma self management (Ostojic, Cvoriscec, Ostojic, Reznifoff & Stripic-Markovic et al. 2005)
- Hypertensive medication compliance (Marquez Contreras, Figuera von Wichmann, Guillen, Figueras et al. 2004)
- Bulimia nervosa outpatient care (Robinson, Perkins, Bauer, Hammond & Treasure et al. 2006)

Gerber, Stolley, Thompson, Sharp and Fitzgibbon (2009) studied the feasibility of using one way text messages to aid weight loss maintenance after a six-month weight loss programme. During a four month weight loss trial of 95 African American women, 42 chose to create 165 personal text messages that included tips on healthy eating and physical activity, they were also able to request the messages at certain times of the day or on certain high risk days such as holidays and weekends. Other women not electing personalised messages were sent general messages by research staff. A client-based software application for text messaging services meant that the service was automated and therefore required little input.

Hawkins, Kreuter, Resnicow, Fishbein and Dijkstra (2008) found that 'tailoring' communications is more likely to engage patients and be effective at changing their health behaviours than sending bulk non-personalised messages. Fjeldsoe, Marshall and Miller (2009) reviewed 14 studies using text messaging for communicating health behaviours (e.g. physical activity, weight management and medication compliance). Their search criteria were; intervention delivered primarily via text messaging, assessed change in health behaviour using pre-post assessment, and publication in English in a peer-reviewed scientific journal. The authors only found two studies that used non-tailored text messaging and these showed among the highest rates for programme attrition. Fjeldsoe et al. (2008) proposed that non-tailored messages are much less engaging for programme participants; engagement and retention are crucial for successful behaviour change.

Joo and Kim (2007) detailed one such study that sent non tailored text messages. They conducted a 12-week community-based weight management programme using text messaging. A total of 927 patients were recruited and attended initial

assessment at a Korean health centre. Once weekly, mobile phones were used to deliver short one way (researcher to participant) text messages on diet, exercise and behaviour modification to participants. Weight, waist circumference and body mass index measurements were taken at baseline and 12 weeks. Four hundred and thirty-three participants (47%) successfully completed the weight management programme. Mean reductions of weight, waist circumference and body mass index of 1.6 kg ($p < 0.001$), 4.3 cm ($p < 0.001$) and 0.6 kg/m² ($P < 0.001$), respectively were found. A post-intervention subject satisfaction survey showed that 71% of participants who completed the 12-week programme thought it effective. The quality of the results is marred by the high attrition rate of 47%. However, it is acknowledged that sending tailored text messages to 927 people would be very time intensive.

A randomized controlled trial (RCT) by Patrick et al. (2009) found that text messages were a useful communication method to promote weight loss in overweight adults. Initial focus groups aided the researchers in developing a prototype of the system. A text message based intervention was designed to help individuals lose or maintain weight over 4 months. Participants were exposed to one of the following two conditions lasting 16 weeks: (1) receipt of monthly printed materials about weight control; (2) an intervention that included personalised text and media messages. Participants in the intervention group could choose the frequency and timing of the messages they received. Each week a different topic such as portion control, self monitoring or pedometer usage was focussed on for these messages. After four months, the intervention group ($n=33$) lost significantly ($p = 0.02$) more weight than the comparison group ($n=32$) (2.88 vs. 0.91 kg, 95% CI -0.34 to -3.60 kg) after adjusting for sex, baseline weight and age. The intervention included teaching

material other than solely text messages; monthly literature and phone calls. This makes determining the precise effects of the daily text messaging system difficult to determine. The authors comment that their previous understanding of brief phone calls to patients and the sending of literature led them to believe that these support materials are inadequate on their own to bring about the extent of weight change observed. They note that those in the study who were comfortable with text messaging may have higher literacy and socioeconomic status than those who would potentially benefit more from weight loss programmes.

Haapala, Barengo, Biggs, Surakka and Manninen (2009) carried out a randomised control study where 125 overweight adults joined either an experimental group ($n=62$) to use a mobile phone based weight loss programme or to a control group ($n=63$) receiving no intervention. By using text messaging, the programme encouraged a gradual reduction of oral intake and participants were asked to report on their daily weight. Participants were sent immediate tailored feedback based on their responses. Outcome data was collected at 0, 3, 6, 9 and 12 months in the experimental group and 0 and 12 months for the control group. At 12 months the experimental group had lost significantly ($p=0.006$) more weight than the control group (4.5 ± 5.0 kg v. 1.1 ± 5.8 kg) and had greater waist circumference losses ($p=0.0001$) (6.3 ± 5.3 cm vs. 2.4 ± 5.4 cm). Haapala et al. (2009) concluded that this particular mobile phone facilitated weight loss programme produced short and long term weight loss results. Although the sample size in this study appears small, the authors had carried out power calculations. A criticism of this study is that no specific dietary or physical activity advice was given to either the control or intervention group, this compounded by the fact that participants were allowed to join other

weight loss groups, could mean that the true effect of the study intervention may be difficult to determine. To deal with this, the authors added this potential participation as a cofactor in the repeated measures ANOVA. Haapala et al. (2009) note that the physical activity and dietary intake data was collected via self reporting – there are well documented accuracy issues with this type of data collection (Lissner et al. 2000).

As a minimal advice, maximal contact intervention, text messaging could open up many possibilities for application in future weight management programmes. Specific mobile phone applications for this purpose are becoming available; however the efficacy of this contact method and these innovative programmes in supporting weight management need to be further investigated (Haapala et al. 2009).

1.7 Rationale

Leicestershire Nutrition and Dietetic Service (LNDS) delivers a 12-week weight management programme entitled LEAP (Lifestyle, Eating and Activity Programme) [Appendix 1]. The programme is a Dietitian-led course comprising 12 weeks of nutrition and physical activity for overweight and obese adults (BMI > 28kg/m² with co morbidities or > 30kg/m²).

After referral to the programme, patients attend an assessment appointment with a Dietitian to discuss the programme, patient and provider expectations and collect initial anthropometric and quality of life data. All participants are set a 5% weight loss target to achieve over the 12-week LEAP programme. LEAP includes nutrition topics such as fats, sugars, label reading, dealing with social pressures to eat and comfort eating. Physical activity sessions (including circuits, hula-hooping, street dance,

frisbee and line dancing) are delivered by qualified fitness professionals through a local authority provider – ‘Active Together’.

Maintaining contact with LEAPers following completion of their course is vital. National obesity guidance recommends regular contact with a practitioner to support long term weight loss outcomes (NICE, 2006). However, frequent direct clinical contact with participants following their initial period of intensive support (LEAP) is costly. Although weekly weight checks are offered after the LEAP course finishes, uptake of these was low; less than 25% of enrolled participants attended. Exit information from post LEAP participants revealed the following reasons for non attendance:

- Lack of motivation
- Change to childcare circumstances
- Costs of travel to venue
- Change in work hours
- Employer no longer able to fund attendance time

This study aimed to fill the knowledge gap of whether text messaging can be effective in promoting a positive weight outcome (weight maintenance or further weight loss) following a weight management group.

Enhancing the current LEAP weight management programme with an additional intervention named ‘LEAP Beep’ involves the addition of remote support by text messaging for participants once they have finished their 12-week LEAP course. This

could provide important improvements in measurable health outcomes and attrition rates.

This research differs from previously published work as 'LEAP Beep' was used as an extension to an existing weight management programme (LEAP). It supported participants to use self monitoring skills with the added benefit of practitioner feedback against measured targets. This study facilitates future roll out of text messaging contact with patients and increases the potential to upscale important two-way weight management support. Text messaging could bridge the gap between the patient and practitioner in a convenient and functional manner that is inexpensive for both parties.

1.8 Hypothesis and research questions

There will be a significant difference between standard care and intervention groups in the following six health variables;

- I. Body mass
- II. Waist circumference
- III. BMI
- IV. Anxiety
- V. Depression
- VI. Quality of life

Research questions

1. Is there a significant relationship between how often the patient texts their data to the researcher and health outcome variables in the intervention group?
2. Is there will be a significant positive relationship between the health variables and variables of lifestyle change in the intervention group;
 - I. Steps walked
 - II. Breakfast consumption
 - III. Fruit and vegetable intake
3. Is there a significant reduction in attrition rates between standard care and intervention groups?

Chapter 2.0 Methods

2.1 Ethical Considerations

Ethical approval for this study was granted from the Leicestershire Northamptonshire and Rutland Research Ethics Committee 1 on May 19th 2010 (Appendix 2). Approval from the Leicestershire County and Rutland Primary Care Trust Research and Development department was granted on June 17th 2010 (Appendix 3). All participants in the intervention arm of the study gave their informed consent to participate. Patient data can be analysed for the purpose of monitoring and improving healthcare under Caldicott principles (Department of Health, 1997), the Data Protection Act (1998) and the NHS Confidentiality Code of Practice (Department of Health, 2003b). Data collection began once ethical approval for the study was agreed.

This study used non-invasive methods to collect measurements. No extra measurements were taken in comparison to those usually taken during this period after dietetic intervention. Body mass, BMI, waist circumference and quality of life measurements at 1 and 12 weeks were taken from existing records held securely by LNDS.

Prior to consent being taken, patients were informed there would be a personal cost of approximately £0.24 - £0.30 each week over the 12 week study (total of approximately £2.88 - £3.60) to send the researcher two text messages containing their data. Participants were informed that no compensation for this was available. Leicestershire Northamptonshire and Rutland Research Ethics Committee were aware of and accepted this lack of compensation. Discussions with previous LEAP

groups not participating in the study felt that sending two messages each week at a cost to themselves was acceptable in relation to perceived health benefits.

Once ethical approval was agreed, the researcher held one group recruitment discussion with the patients interested in participating in the study and distributed the Patient Information Sheets that bore initial information concerning the study (Appendix 4). The researcher also carried out four telephone conversations with patients unable to attend the face to face discussion; the Patient Information Sheet was read out in these instances. The researcher emphasised that participation in the study was entirely voluntary and that non-participation or withdrawal would not negatively affect ongoing dietetic treatment. Participants were asked to express their interest to participate by telephone contact with the researcher within one week.

Eighteen patients completed consent forms (Appendix 5). All patients received copies of their consent form (another copy was retained in the service's dietetic case notes) and their own Participant Instruction Booklet for further information about the study (Appendix 6). The instruction booklet contained contact information and times of the researcher's availability. All correspondence and literature for patients was proof read by dietetic colleagues and written in jargon-free, layman's terms to make their purpose clear and concise. All written correspondence to the participants and their GP was on letter headed paper that bore the logo of Leicestershire County and Rutland PCT and the University of Chester. Each participant's GP was informed of their participation in the study (Appendix 7). All participants consented to this communication.

2.2 Population

All participants in this study were National Health Service patients recruited from dietetic referrals to LNDs. Local health professionals including General Practitioners and Practice Nurses referred patients to be seen by Dietitians registered by the Health Professions Council. A minority of referrals received were from patients themselves. The patients comprising the study groups were a self-selected group; wilfully opting in to seek Dietetic support and were given the choice of dietetic intervention through either individual one to one appointments or group weight management sessions. All patients in the study chose group weight management sessions and were assessed at outpatient appointments in clinical settings across Leicestershire. Group sessions were delivered in a community venue.

2.2.1 Inclusion and exclusion criteria

An administrative assistant (part of the clinical care team) screened referrals for suitability using the study inclusion and exclusion criteria detailed below.

Study inclusion criteria

- BMI (defined as weight / height²) more than 30 kg/m²
- BMI more than 28 kg/m² + established co-morbidities (hypertension, diabetes, cardiovascular disease, hyperlipidaemias etc)
- Aged greater than 18 years
- No parallel participation in a commercial weight loss programme

- Completion of LNDS' LEAP programme (defined as attendance of greater than 50% of sessions)
- Ability to use text messaging

Study *exclusion* criteria

- BMI less than 30 kg/m²
- BMI more than 28 kg/m² without established co-morbidities (hypertension, diabetes, cardiovascular disease, hyperlipidaemias etc)
- Aged less than 18 years
- Parallel participation in a commercial weight loss programme
- Non completion of LNDS' LEAP programme
- No ability to use text messaging

2.2.2 *Participants*

Patients for whom the primary reason for referral was obesity were offered an assessment appointment with the lead researcher, and then attended the 12-week LEAP weight management group – which was ongoing at the time of the study. Patients unable to send and or receive text messages were excluded from the study but were allowed to join the LEAP group.

Following ethical approval, timescales allowed for two cohorts of post-LEAP group patients ($n=29$) meeting inclusion criteria to be approached for potential recruitment to the intervention group. Eighteen consenting patients were recruited to the intervention group of the study.

LNDS collected body mass, waist, BMI, anxiety, depression and quality of life outcomes as standard therefore no informed consent was necessary from the standard care group ($n=17$). Retrospective measurements were taken from the standard care group.

None of the patients had previously attended LNDS' LEAP group. None of the patients took anti-obesity medication (Orlistat) throughout the study period.

2.1.3 Participant Characteristics

The relevant characteristics of the study population are presented in Table 1

Table 1. Baseline characteristics by group: overweight and obese Leicestershire adults

	Intervention ($n=17$)	Control ($n=17$)
Variable	Mean \pm SD	Mean \pm SD
Age (years)	58.3 \pm 12.1	59.1 \pm 9.5
Sex		
Males	7	4
Females	10	13
Body mass (kg)	97.0 \pm 14.1	98.2 \pm 15.4
BMI (kg/m^2)	35.6 \pm 5.0	35.1 \pm 5.2
Waist circumference (cm)	114.4 \pm 12.3	115.6 \pm 12.2

2.2 - Study design

This controlled cohort study ran from April 2010 – October 2010. The study used clinical (anthropometric) and subjective outcomes to evaluate the successfulness of the text message based intervention. The study also included a retrospective analysis of previously collected longitudinal data from participants in previous LEAP

groups. The control group (standard care) received no active intervention throughout the study but were able to attend optional drop-in weight checks. The intervention group could also attend weight checks if they desired. One intervention group patient dropped out due to care commitments of an older relative.

2.2.1 Independent and dependent variables

The dependent variables were;

- Body mass measured using adult digital weighing scales;
- Waist circumference measured using a constant tension waist tape;
- BMI was calculated using the Garrow and Webster (1985) method.
- Anxiety and depression measured using the validated 'Hospital Anxiety and Depression scale' (Zigmond & Snaith, 1983) [Appendix 8]
- Quality of life measured using the validated 'Impact of Weight on Quality of Life' tool (Koloktin, Crosby, Kosloski & Williams, 2001) [Appendix 9]

The independent variable was;

- Participation in a standard care group or the intervention group

These specific variables were chosen to represent both clinical and patient centred outcomes.

2.3 Measurements and Materials

All measurements were collected by a trained specialist obesity dietitian. Anthropometric and patient centred (subjective) data was collected at week 1 and week 12 from the intervention group and retrospectively from the control group as

detailed in table 2. Collected data was compared with retrospective data at 1 and 12 weeks from patients who received standard care.

Table 2. Method of anthropometric and patient centred data collection at weeks 1 and 12

Anthropometric measurements			
Measure	Instrument	Technique / tool	Administrator
Body Mass (kg)	Marsden portable electronic weighing scales (Marsden M2020L, Marsden, Oxfordshire, UK) Maximum weight capacity 200kg Graduations of 0.1kg. Calibrated on 12/10/09 and 09/09/10	Placed on firm, flat surface for accurate measurement, subject weighed in consistent weight clothing (Appendix 10).	Researcher
Waist (cm)	Constant tension waist circumference tape	Measured at the midpoint between the lower margin of the last palpable rib and the top of the iliac crest. (Appendix 11)	Researcher
BMI (kg/m ²)	Marsden portable electronic weighing scales (Marsden M2020L, Marsden, Oxfordshire, UK)	Weight / (height ²) (Garrow & Webster, 1985)	Researcher
Patient centred measurements			
Anxiety and depression	Validated tool	Hospital Anxiety Depression validated scale (Zigmond & Snaith, 1983) [Appendix 8]	Participant
Quality of life	Validated tool	Impact of Weight on Quality of Life (IWQOL) validated tool (Koloktin et al., 2001) [Appendix 9]	Participant

2.3.1 Validity of tools

- Impact of Weight on Quality of Life [IWQOL] (Koloktin et al., 2001).

The IWQOL is a commonly used instrument to measure weight-related quality of life. It is a 31-item questionnaire to measure quality of life in relation to weight on a 5-point scale. Five scales are derived: physical function, self-esteem, sexual life, public distress, and work. Koloktin and Crosby (2002) demonstrated that the IWQOL displays high internal consistency (alpha = 0.96 for total score, alpha = 0.82 to 0.94 for the five individual scales) and satisfying convergent and discriminant validity.

- Hospital Anxiety and Depression Scale [HADS] (Zigmond & Snaith, 1983)

The HADS is a self-assessment scale developed for detecting states of depression and anxiety. Bjelland, Dahl, Haug and Neckelmann (2002) reviewed 747 papers that used the HADS and found it to be a reliable instrument. Most factor analyses demonstrated a two-factor solution in good accordance with the HADS subscales for Anxiety (HADS-A) and Depression (HADS-D), respectively. The correlations between the two subscales varied from 0.40 to 0.74 (mean 0.56). Cronbach's alpha for HADS-A varied from 0.68 to 0.93 (mean 0.83) and for HADS-D from 0.67 to 0.90 (mean 0.82). The sensitivity and specificity for both HADS-A and HADS-D was found to be approximately 0.80. The correlation between HADS and other frequently administered questionnaires ranged from 0.49 to .083. The anxiety and depressive subscales are also valid measures of severity of the emotional disorder.

2.4 Procedures

No text messages were sent to or from the Dietitian in either the intervention or standard care groups during the standard LEAP group. After completing LEAP, two

cohorts were offered participation in the 12-week text messaging intervention (LEAP Beep). Patients from both these cohorts consented to take part in the intervention arm of the study.

The intervention group attended an instruction session on the final week of the LEAP programme where the text messaging intervention (LEAP Beep) was discussed, specifically the three daily lifestyle behaviours that were being measured: steps taken, fruit and vegetable consumption and breakfast consumption.

2.4.1 Lifestyle and behavioural markers

Three measures were chosen as proxy markers of a healthy lifestyle because along with regular self monitoring, they are regarded as being some of the common lifestyle behaviours of successful weight losers;

- Physically active lifestyle
- Breakfast eating
- Less dietary fat, more healthy foods

(Wing & Hill, 2001); Elfhag & Rossner, 2004)

2.4.1.1 Physically active lifestyle

Consenting participants were each given one Silva pedometer (Step Counter model 56012, Silva Sweden AB, Sweden) and briefed on its correct usage, including

placement to achieve the most accurate reading and daily reset procedure. A manufacturer's instruction booklet was given with each pedometer.

Prior to the data collection phase participants were instructed to wear the pedometer for a three day period to include at least one weekend day to determine an average step count and subsequently a step target. Patients contacted the lead researcher (via telephone or face to face contact) with their three pedometer readings. Based on these readings an average was calculated and 500 steps added to this figure to create an increase in steps to achieve. This step target calculation was based on recommendations from Tudor-Locke, Hatano, Pangrazi and Kang (2008). During the LEAP Beep intervention participants were asked to send their pedometer reading as the five digit digital display from the front of the pedometer. For example a pedometer reading of 08536 steps would be sent as 08536.

2.4.1.2 Breakfast Eating

Participants were asked to report whether or not they ate breakfast as a yes / no response;

Did not eat breakfast was sent as 'BF no'

Did eat breakfast was sent as 'BF yes'

2.4.1.3 Less dietary fat, more healthy foods

All participants were given the same target of consuming five portions of fruit and vegetables each day. All participants were given Department of Health literature '5 a day, what's it all about?' detailing which foods and amounts counted toward their fruit and vegetable intake (Department of Health, 2003a). Fruit and vegetable portion sizes had also been frequently discussed throughout the LEAP programme. Intervention group participants were asked to send their data on fruit and vegetable consumption in the following manner:

Three fruit and vegetable portions consumed was sent as 'FV3'

Five fruit and vegetable portions consumed was sent as 'FV5'

2.4.2. Maintenance of confidentiality of text messages

Advice was sought from Leicestershire County and Rutland Primary Care Trust Information Governance managers to optimise confidentiality of patient data. Any data received from NHS patients from must be received confidentially and be included in their dietetic case notes. Information governance stipulated that data from patients should be sent as a coded data set as described in section 2.4.1.

Conventional text messaging is an unsecured mode of communication between practitioner and patient. In order to comply with the NHS Confidentiality Code of Practice (2003) a BlackBerry device (BlackBerry 8700v Enterprise, BlackBerry: Ontario, Canada) was used to convert email to text message and vice versa. To

enable this, a conversion application (SMS2desk, Cortado SMS2Desk, Cortado: Colorado, USA) was downloaded onto the BlackBerry device. This application was synchronised with the researcher's Microsoft Outlook (Microsoft Outlook 2007, Microsoft: Washington, USA) email system. Email to text messaging conversion enabled the researcher to print off and document all communication from practitioner to 'LEAP Beep' participant. This would not have been possible using a conventional mobile phone for text messaging. Using this method of data conversion satisfied PCT Information Governance managers that the data of patients in the intervention arm was protected sufficiently. Participants were also instructed that text messages were for the sole purpose of communicating data about lifestyle behaviours – any other questions or comments for the Dietitian were to be made via face to face contact or a telephone call.

2.4.3 Communication of lifestyle behaviours sent between participants and the researcher

Participants were instructed in the Participant Instruction Booklet (Appendix 6) to send data on all three lifestyle behaviours as one text message to reduce patient costs and reduce researcher message burden. Participants could wear their pedometer, record breakfast consumption and fruit and vegetable intake everyday if desired. However, participants were instructed to send the researcher data on their three lifestyle behaviours on two days each week; one weekday and one weekend day.

The researcher's computer (Dell Latitude D630, Dell, Texas, USA) was used to send and receive participant data. The BlackBerry mobile phone was used occasionally when the computer was not available (for example, at weekends and evenings). Participants were sent an initial tester text message (read 'test message') to ensure the correct mobile phone number was provided. Participants were instructed to save the researchers BlackBerry's mobile phone number to minimise manual phone number entry error and maximise security of the patient's information.

Participants were sent text messages on Mondays and Fridays for the duration of the study requesting their weekend and weekday data respectively. Details of the researcher to participant dialogue are given in Appendix 10. Data sent by each participant was compared to their individual targets for step counts and to the standard target for fruit and vegetable and breakfast consumption.

If the participant met all their targets for steps, fruit and vegetable and breakfast intake, a positive message was sent back to them such as 'well done you have met all of your targets, keep up the good work'. If the step target was achieved for three consecutive measurements, a new target was set according to Tudor-Locke and Bassett (2008). If the participant failed to reach one or more of their targets, they were sent an encouraging response such as 'you are almost at your target' as well as a practical tip relating to their failed target such as 'try parking further from your destination'; 'remember that dried fruit counts towards fruit & vegetables' or 'try making breakfast the night before' to help them meet that particular lifestyle target later in the week. All messages sent in response to patients were taken from a 'bank' of comments written by the researcher (Appendix 13) to increase fruit,

vegetable and breakfast consumption and step counts. Using this 'bank' also served to minimise manual entry error.

If no response to the request for data was received on the day of sending, a second identical request message was sent the following day and the third day if necessary.

2.5 Participant Satisfaction

At the end of the intervention, all participants were asked to complete an anonymous Patient Satisfaction Survey (Appendix 14) to gauge their opinions on the text messaging intervention and help inform future roll out.

2.6 Data Management

All data received from participants was stored on a Microsoft Excel database (Microsoft Excel 2007, Microsoft: Washington, USA). Patient data was not identifiable by name, initial, hospital number or other distinguishing feature. Instead, the last three digits of the participant's mobile telephone number were used as an identifier, this maintained confidentiality and anonymity. The two quality of life tools and the participant satisfaction survey were also allocated the same three digit identifier. Information from the completed tools and survey was entered onto the database corresponding to the tool identifier number.

Data collected during the study was used for no other purpose other than the study. All intervention and standard care data was securely held on the hard drive of a NHS computer (Dell Latitude D630, Dell, Texas, USA) that was username and password protected as well as fitted with SafeBoot encryption (McAfee, California, USA) This

computer was only available to the researcher. The BlackBerry mobile phone (primarily used as a router to convert email to text messaging) was occasionally used for data exchange and was username and password protected. All data was backed up on a password protected memory stick (Kingston Data store Vault, 2GB, Kingston; California, USA).

2.7 Statistical analyses

All statistical analyses in this study were conducted using the Statistical Package for the Social Sciences (SPSS) programme (Version 17.0, SPSS Inc, Chicago, IL, USA). Prior to analysis study data was coded for anonymity and screened. Data used in this study was quantitative.

2.7.1 Hypothesis and research questions

The study aimed to determine the effectiveness of 'LEAP Beep' a text message based intervention, on weight management outcomes in overweight and obese Leicestershire adults by testing the following null hypothesis:

Null Hypothesis: Participant's body mass, waist circumference, BMI, anxiety, depression and quality of life did not change significantly after taking part in the text messaging intervention, compared to a control group.

The study also aimed to answer the following research questions:

1. Is there a significant relationship between how often the patient texts their data to the researcher and health outcome variables in the intervention group?
2. Is there will be a significant positive relationship between the health variables and variables of lifestyle change in the intervention group;

IV. Steps walked

V. Breakfast consumption

VI. Fruit and vegetable intake

3. Is there a significant reduction in attrition rates between standard care and intervention groups?

2.7.2 Descriptive analyses

To understand the characteristics of the study population descriptive statistics were carried out. Statistical tests such as the Kolmogorov-Smirnov and Shapiro-Wilk can assess for normality of distribution. A non significant result ($P>0.05$) indicates significance (Pallant, 2005). There were less than 100 samples in this analysis ($n=34$) therefore Coakes and Steed (2007) recommend consulting the Shapiro-Wilk statistic to examine for normality of distribution.

Normally distributed data was reported with the mean and standard deviation. Non normally distributed data was presented as the median and the range. All reported P

values are for two sided tests, with effects considered statistically significant at the level of $P < 0.05$.

2.7.3 Inferential statistics

The data in this study was ratio as body mass (kg), waist circumference (cm), anxiety, depression and quality of life have order, distance and origin.

The independent variable was participation in the control/standard care or intervention group (LEAP Beep). The dependent variables were body mass (kg), waist circumference (cm), BMI (kg/m^2) anxiety, depression and quality of life. Repeated measures were the data collected at baseline of 'LEAP Beep' (week 1) and at the intervention end (week 12).

Hypothesis: There will be a significant difference between the standard and intervention groups in the following six health variables; body mass, waist circumference, BMI, anxiety, depression and quality of life.

The appropriate statistical tests were Paired t-tests to test for differences between variables within the groups. This statistical test required data to be normally distributed and have homogeneity of variance. There were less than 100 samples in the analysis ($n=34$) therefore Coakes and Steed (2007) recommend consulting the Shapiro Wilk statistic to examine for normality of distribution. To determine the variance or equality of the two groups, a test of homogeneity of variance was carried

out using Levene's statistic. For non-normally distributed data Wilcoxon Signed ranks tests were used.

To test for differences within the groups, Independent T tests were used, these also required normal distribution and homogeneity of variance. Mann Whitney U tests were used for non-normally distributed data.

Research question 1: Is there a significant relationship between how often the patient texts their data to the researcher and health outcome variables in the enhanced group? This data contained a combination of normally and non-normally data therefore Pearson's and Spearman's test were used respectively.

Research question 2: To determine whether there will be a significant relationship between the health variables and variables of lifestyle change; steps walked, breakfast consumption and fruit and vegetable intake. This data contained a combination of normally and non-normally data therefore Pearson's and Spearman's test were used respectively.

Research question 3: To determine whether there will be a significant improvement in attendance rates between standard and enhanced groups. The data was non-normally distributed therefore a Mann Whitney U test was used to show differences between the groups.

3.0 Results

3.1 Participation and Attrition

Twenty nine patients that had previously completed the LEAP programme were invited to take part in the additional intervention group (LEAP Beep). Of this group, nine participants refused to take part and two participants did not meet inclusion criteria because they did not have a mobile phone. One patient dropped out after giving consent due to family issues at home. Retrospective data was collected from a control group of seventeen participants. Figure 3 represents the recruitment journey.

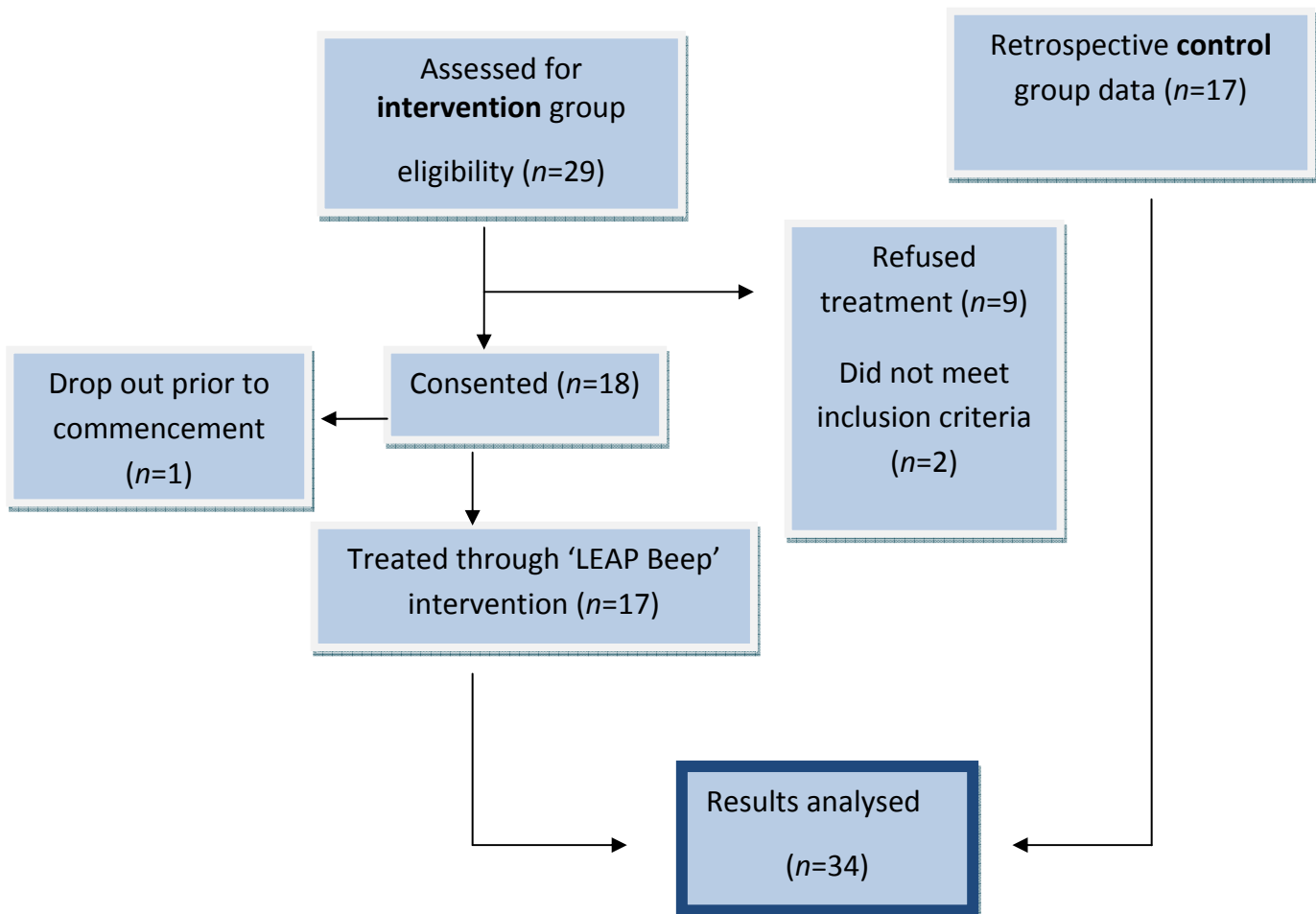


Figure 3. Intervention and control group participation flowchart

3.1.1 Group differences at baseline

To assess for group differences at baseline between control and intervention groups, Independent t tests were carried out on parametric data (waist circumference and

quality of life). Mann Whitney U tests were carried out on parametric data (weight, waist circumference, age, depression and anxiety) (Appendix 15). No significant differences were found between baseline intervention and control groups for waist circumference ($p=0.771$); quality of life ($p=0.241$); body weight ($p=0.823$); BMI ($p=0.679$); age ($p=0.890$); depression ($p=0.050$) or anxiety ($p=0.836$).

3.2 Pre and post intervention changes

3.2.1 Within group differences

Within groups, Paired T tests and Wilcoxon Signed ranks tests were used to detect the significance of changes in normally and non-normally distributed data respectively.

3.2.1.1 Intervention group 'LEAP Beep' differences

Due to the low sample numbers some data were non-normally distributed. For comparative purposes between and within groups, descriptive information has been presented as mean \pm Standard Deviation (SD) for all data. Appendix 16 uses histograms to describe the distribution of data for three variables:

Participation in the intervention group 'LEAP Beep' yielded a significant ($p=0.013$) weight loss of 1.6kg (1.6% body mass) over the 12-week intervention period. Significant ($p=0.006$) changes were also noted in waist circumference and BMI (2.2cm ($p=0.006$); -0.6kg/m² ($p=0.015$)).

For quality of life (QOL), anxiety and depression scores, a reduction in score points represents an improvement in that parameter. QOL improved with a mean reduction of 6.8 points, equivalent to an increase in QOL of 10.3% ($p=0.039$). Mean anxiety levels improved (6.6 \pm 3.8 points vs. 6.5 \pm 3.2 points) ($p=0.495$) throughout the

intervention. Mean depression levels also reduced (2.8 ± 2.7 points vs. 2.6 ± 2.9 points) ($p=0.572$) pre intervention to post intervention. Table 3 highlights the changes detected within the intervention group. Appendix 17 includes some raw data on health variables from the intervention group pre and post intervention.

Table 3. Mean \pm SD values for all intervention group health variables

Variable	Intervention ($n=17$)				
	Mean \pm SD		Actual change	% Change	p value
	PRE Intervention	POST Intervention			
Body mass (kg)	97.0 ± 14.1	95.4 ± 15.0	-1.6	-1.6	0.013*
Waist circumference (cm)	114.4 ± 12.3	112.2 ± 11.9	-2.2	-1.9	0.006*
BMI (kg/m^2)	35.6 ± 5.0	35.0 ± 4.9	-0.6	1.8	0.015*
QOL (points)	65.8 ± 17.7	58.9 ± 16.8	-6.8	-10.3	0.039*
Anxiety (points)	6.6 ± 3.8	6.5 ± 3.2	-0.1	1.5	0.495
Depression (points)	2.8 ± 2.7	2.6 ± 2.9	-0.2	7.1	0.572

*Significant ($p<0.05$) change from baseline (PRE) to POST intervention

3.2.1.2 Control group differences

Over a 12-week period after completion of LEAP, the control group displayed a mean weight gain of 0.7kg (0.7% body mass). Mean BMI also increased 7.5% ($p=0.046$) Significant ($p=0.035$) undesirable changes were also noted in waist circumference measurements; a mean increase of 1.5cm (1.3%).

Mean QOL scores increased by one point (1.3%) ($p=0.039$). Mean anxiety scores improved in the control group (6.7 ± 5.6 points vs. 6.6 ± 4.4 points). Mean depression scores worsened by 3.9%. These increases in QOL and depression scores represent

a decline in these clinical parameters. Table 4 highlights the changes detected within the control group.

Table 4. Mean \pm SD values for all control group health variables

Variable	Control (n=17)				
	Mean \pm SD		Actual change	% Change	Difference between groups (p value)
	PRE Intervention	POST Intervention			
Body mass (kg)	98.2 \pm 15.4	98.9 \pm 15.1	+0.7	+0.7	0.227
Waist circumference (cm)	115.6 \pm 12.2	117.1 \pm 10.8	+1.5	+1.3	0.035*
BMI (kg/m ²)	35.1 \pm 5.2	35.8 \pm 4.9	+0.7	+7.5	0.046*
QOL (points)	76.5 \pm 32.6	77.5 \pm 32.3	+1	+1.3	0.810
Anxiety (points)	6.7 \pm 5.6	6.6 \pm 4.4	-0.1	1.5	0.874
Depression (points)	4.9 \pm 3.4	5.1 \pm 3.8	+0.2	+3.9	0.325

*Significant (p<0.05) change from baseline (PRE) to POST intervention

3.2.2 Between group differences

A significant difference ($p=0.006$) was found between the intervention and control groups for body mass (2.3kg). A significant ($p=0.0005$) difference was found in waist circumference and BMI between the groups (3.7cm; $p=0.0005$, 1.5kg/m²; $p=0.003$). QOL also improved (7.8 points) but not significantly ($p=0.134$). Both groups reduced anxiety however; no differences in anxiety change scores were detected between the groups. Depression scores changed by 4 points -representing an improvement in

depression, this was not significant ($p=0.228$). Table 5 highlights the changes detected between the control and intervention groups.

Table 5. Actual changes for all health variables between groups

Variable	Intervention Actual change	Control Actual change	Between group difference	Difference between groups (p value)
Body mass (kg)	-1.6	+0.7	2.3	0.006*
Waist circumference (cm)	-2.2	+1.5	3.7	0.0005*
BMI (kg/m^2)	-0.6	+0.7	1.5	0.03*
QOL (points)	-6.8	+1	7.8	0.134
Anxiety (points)	-0.1	-0.1	0	-
Depression (points)	-0.2	+0.2	-0.4	0.228

*Significant ($p<0.05$) difference between control and intervention groups.

3.3 Relationship between text messaging correspondence and health variables

A maximum of 24 text messages could have been sent from the intervention group.

A mean of 23 ± 1.7 text messages were received by the researcher.

Normally distributed data was analysed for significant relationships using a Pearson's test. Non-normally distributed data was analysed using a Spearman's test.

Table 6 shows that there were no significant relationships found between the frequency of text messaging and the six variables of health (body mass, waist circumference, BMI, quality of life, anxiety and depression).

Table 6. Relationship between text messaging correspondence and health variables

Health Variable	P value	Correlation (r value)
Body mass (kg)	0.877	-0.041
Waist circumference (cm)	0.552	0.155
BMI (kg/m ²)	0.703	0.100
Quality of Life	0.591	-0.140
Anxiety	0.785	0.071
Depression	0.049	-0.214

3.4 Intervention group changes in variables of lifestyle change

Mann Whitney U tests were used to assess for differences between steps walked and breakfast consumption in the intervention group. To identify differences between the start and end of the study, a mean of the values for each variable was taken from the first three returned text messages of the study and compared to the final three messages (Table 7) Steps walked increased by 16.4%, fruit and vegetable intake by 5.4%, no significant ($p=0.317$) change was observed in breakfast consumption.

Table 7. Mean \pm SD values for intervention group lifestyle variables

Variable	Mean \pm SD		Actual change	% Change	Difference between groups (p value)
	PRE Intervention	POST Intervention			
Steps walked	6066 \pm 2290	7260 \pm 3258	+1194	+16.4	0.055
Fruit and vegetable intake (portions/day)	5.3 \pm 1.2	5.6 \pm 1.4	+0.3	+5.4	0.249
Breakfast consumption (max 3)	3 \pm 0	2.9 \pm 0.49	+0.1	3.3	0.317

3.5 Relationship between the health variables and variables of lifestyle change in the intervention group

Normally distributed data was analysed for significant relationships using a Pearson's test. Non-normally distributed data was analysed using a Spearman's test.

A significant ($p=0.003$) modest negative correlation ($r=-0.671$) was found between number of steps walked and depression (Figure 4). The correlation co-efficient of 45.0% demonstrates that 45.0% of the total variance of depression is due to steps walked.

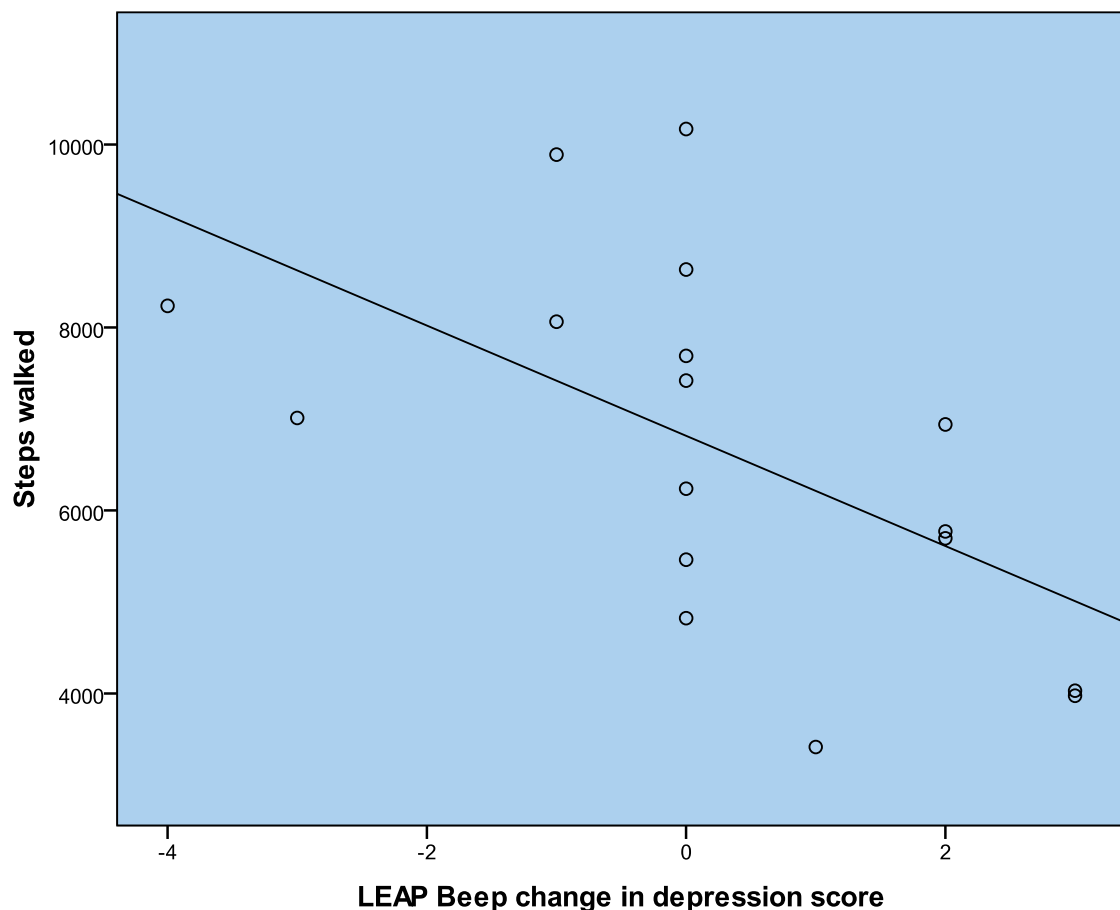


Figure 4. Negative correlation of increased steps and improvement in depression score

No other significant correlations were found between other health variables and variables of lifestyle change (Table 8).

Table 8. Relationships between health variables and lifestyle variables

Health variable	Lifestyle variable	P value	Correlation (r value)
Body mass (kg)	Steps	0.594	0.139
	Fruit and vegetables	0.440	-0.200
	Breakfast	0.387	-0.224
Waist circumference (cm)	Steps	0.572	0.148
	Fruit and vegetables	0.129	-0.383
	Breakfast	0.489	-0.180
BMI (kg/m²)	Steps	0.411	0.213
	Fruit and vegetables	0.433	-0.204
	Breakfast	0.424	-0.208
Anxiety	Steps	0.282	-0.277
	Fruit and vegetables	0.143	0.370
	Breakfast	0.079	0.438
Depression	Steps	0.003*	-0.671
	Fruit and vegetables	0.647	0.120
	Breakfast	0.285	-0.275
Quality of Life	Steps	0.983	-0.006
	Fruit and vegetables	0.143	0.370
	Breakfast	0.418	-0.210

*Significant (p<0.05) relationship between lifestyle variable and health variable

3.6 Changes in attendance rates between intervention and control groups

Attendance data was non-normally distributed therefore a Mann Whitney U test analysed the differences between these independent groups. Both control and intervention groups were able to attend a maximum of 16 follow up weight checks

throughout the study period. The intervention group attended significantly ($p=0.0005$) more appointments than the control group as highlighted in table 9.

Table 9. Mean attendance differences by group

Group	Attendance Mean \pm SD	<i>p</i> value
Intervention	4.4 \pm 2.6	0.0005*
Control	1.7 \pm 1.3	

*Significant ($p<0.05$) relationship between lifestyle variable and health variable

3.7 Patient satisfaction survey

Fourteen completed surveys (82%) (Appendix 14) were returned from the intervention group. Participant satisfaction with the intervention was high, as is shown in table 10. Fourteen participants (100%) strongly agreed or agreed they were given enough information prior to participation in the intervention, found the programme easy to use and were happy with the frequency of practitioner contact. Fourteen participants (100%) strongly agreed or agreed they were happy with the step and fruit and vegetable tips they received and that the intervention helped them maintain or improve those lifestyle variables. One participant selected neither agree nor disagree for satisfaction with the breakfast tip. Fourteen participants (100%) strongly agreed or agreed the researcher encouraged them to make lifestyle change and that overall they were satisfied with the intervention.

Table 10. Patient Satisfaction Survey results

Question number	Question	Frequency	%	<i>n</i>
1	I was given enough information about the text messaging programme before I took part	Strongly agree	93	13
		Agree	7	1
		Neither	0	0

		Disagree	0	0
		Strongly disagree	0	0
2	I found the text messaging programme easy to use	Strongly agree	86	12
		Agree	14	2
		Neither	0	0
		Disagree	0	0
		Strongly disagree	0	0
3	I was happy with how many times I was contacted via text message during the 12 week programme	Strongly agree	86	12
		Agree	14	2
		Neither	0	0
		Disagree	0	0
		Strongly disagree	0	0
4	I was happy with how long the dietitian took to respond to my message	Strongly agree	86	12
		Agree	14	2
		Neither	0	0
		Disagree	0	0
		Strongly disagree	0	0
5	If I didn't meet my step target, I was happy with the tip I received to help me increase it	Strongly agree	93	13
		Agree	7	1
		Neither	0	0
		Disagree	0	0
		Strongly disagree	0	0
6	If I didn't meet my fruit and vegetable target, I was happy with the tip I received to help me increase it	Strongly agree	86	12
		Agree	14	2
		Neither	0	0
		Disagree	0	0
		Strongly	0	0

		disagree		
7	If I didn't meet my breakfast target, I was happy with the tip I received to help me increase it	Strongly agree	64	9
		Agree	29	4
		Neither	7	1
		Disagree	0	0
		Strongly disagree	0	0
8	I felt that the text messaging programme has helped me to maintain or improve the amount of steps I walk each day	Strongly agree	78	11
		Agree	21	3
		Neither	0	0
		Disagree	0	0
		Strongly disagree	0	0
9	I felt that the text messaging programme has helped me to maintain or improve the amount of fruit and or vegetables I eat	Strongly agree	86	12
		Agree	14	2
		Neither	0	0
		Disagree	0	0
		Strongly disagree	0	0
10	I felt that the text messaging programme has helped me to maintain or improve how often I eat breakfast	Strongly agree	78	11
		Agree	21	3
		Neither	0	0
		Disagree	0	0
		Strongly disagree	0	0
11	I felt that the dietitian encouraged me to make positive lifestyle changes	Strongly agree	93	13
		Agree	7	1
		Neither	0	0
		Disagree	0	0
		Strongly disagree	0	0

12	Overall, I felt satisfied with the text messaging programme	Strongly agree	100	14
		Agree	0	0
		Neither	0	0
		Disagree	0	0
		Strongly disagree	0	0

Table 11 shows additional comments made by the intervention group. Overall very positive comments from participants are feedback. One participant would have liked keep the pedometer. Many participants comment that LEAP Beep helped motivate them and enjoyed working towards goals that helped maintain weight loss during the original LEAP intervention.

Table 11. Additional Patient Satisfaction Survey comments

Additional comments
Gave me motivation and help to lose weight
The text messaging programme helped me to continue with my weight loss and helped me to realise how many steps I needed to be doing
I think that the step counter should have been give to you for good. I am finding that not having one I have slipped back to not doing the walking as much.
I found the text messages very useful, reminded me not to forget my walking and I do feel that I am much fitter, having regular exercise. I am now able to keep walking and eat healthier-it has become part of my way of living. Thanks to Eleanor.
I enjoyed taking part in the text messaging programme. I found it very helpful and very motivating; thank you and I will continue to lose more weight.
The programme helped me maintain my weight loss
When you are feeling low because you didn't meet a target the responses also helped to bring you back up and motivate you to carry on without leaving you feeling guilty. Thank you for the opportunity to take advantage of this programme, I enjoyed it.
The programme changed my lifestyle by incorporating walking into my weekends, with a walk in the country instead of a shopping trip. During the working week I walk the long way home, purely to add more steps to my day. I eat a lot of fruit at work, but have made a conscious effort to fit more fruit into the weekends. I will keep these changes up now I have completed the programme

4.0 Discussion

4.1 Summary of main findings

National guidance (NICE, 2006) recommends that community weight loss programmes such as LEAP should provide follow up for participants once they have completed the course. This study aimed to determine the effectiveness of the 'LEAP Beep' text messaging intervention, on weight management outcomes in overweight and obese Leicestershire adults.

Hypotheses :

There will be a significant difference between standard care and intervention groups in the following six health variables;

- I. Body mass
- II. Waist circumference
- III. BMI
- IV. Anxiety
- V. Depression
- VI. QOL

A significant difference ($p=0.006$) was found between the intervention and control groups for body mass. A difference ($p=0.0005$) was found in waist circumference and BMI between the groups ($p=0.003$), for these variables the hypotheses are supported. No differences in anxiety change scores were detected. No significant differences in QOL or depression were observed ($p=0.134$; $p=0.228$).

Aim 1: To determine whether there was a significant relationship between how often the patient texted their data to the researcher and health outcome variables in the intervention group

No significant relationships were found between the frequency of text messaging and the six variables of health: body mass, waist circumference, BMI, QOL, anxiety and depression ($p=0.877$; $p=0.552$; $p=0.703$; $p=0.591$; $p=0.785$; $p=0.049$).

Aim 2: To determine whether there was a significant positive relationship between the health variables and variables of lifestyle change in the intervention group; steps walked; breakfast consumption; fruit and vegetable intake.

A significant ($p=0.003$) modest negative correlation ($r=-0.671$) between steps walked and an improvement in depression was found. The correlation co-efficient of 45.0% indicates that 45.0% of the total variance of depression is due to steps walked.

Aim 3: to determine whether there was a significant reduction in attrition rates between standard care and intervention groups

The intervention group attended significantly ($p=0.0005$) more appointments than the control group (4.4 ± 2.6) vs. (1.7 ± 1.3)

4.2 Changes in health variables

4.2.1 Body mass

National obesity guidance recommends practitioners collect body mass (weight) and height to calculate BMI and use this figure alongside waist circumference to assess

the risks from overweight and obesity (NICE, 2006). Body mass is one of the simplest and most useful anthropometric measurements to collect.

Participants in the 12-week LEAP Beep intervention lost a mean weight of 1.6kg (1.6%) (pre 97.0 ± 14.1 kg; post 95.4 ± 15.0 kg) ($p=0.013$). This demonstrated that LEAP Beep is an effective platform for supporting participants to achieve further weight loss following an initial intensive weight loss group (LEAP). Furthermore, control participants (optional attendance at weight checks) gained weight 0.7kg (0.7%) during the 12 week period.

The weight loss observed in the intervention group met NICE obesity guidance for the best-practice standards for community based weight management programmes. NICE recommends aiming for a realistic healthy target weight; weight loss of 5–10% and a maximum weekly weight loss of 0.5–1 kg (NICE, 2006).

Supporting patients to achieve modest amounts of weight loss leads to widely recognised health benefits in many important clinical parameters (Table 12.) Jung (1997) described the benefits of a 10% (10kg) weight loss in a 100kg patient. Benefits were in described in relation to mortality; blood pressure; angina; lipids and diabetes.

Table 12. Benefits of a 10 kg weight loss

Mortality	<ul style="list-style-type: none"> • 20-25% fall in total mortality • 30-40% fall in diabetes related deaths • 40-50% fall in obesity related cancer deaths
Blood pressure	<ul style="list-style-type: none"> • Fall of 10 mmHg systolic pressure • Fall of 20 mmHg diastolic pressure
Angina	<ul style="list-style-type: none"> • Reduced symptoms by 91 % • 33% increase in exercise tolerance

Lipids	<ul style="list-style-type: none"> • Fall by 10% in total cholesterol • Fall by 15% in LDL cholesterol • Fall by 30% in triglycerides
Diabetes	<ul style="list-style-type: none"> • Reduces risk of developing diabetes by > 50% • Fall of 30-50% in fasting blood glucose • Fall of 15% in HbA1c

(Jung, 1997)

The pre intervention weight in the intervention (97.0 ± 14.1 kg) and control groups (98.2 ± 15.4 kg) meant that the benefits presented below were relevant to the study population through similarities in weight. Evaluation of the original LEAP programme has shown an average weight loss of 4.1kg (3.8%) [Appendix 18]. This prior weight loss combined with that demonstrated through LEAP Beep (1.6kg) ensures participants are over 50% (5.7kg) of the way towards a 10kg weight loss at 6 months of dietetic input. Throughout the LEAP and LEAP Beep interventions much discussion takes place around the fact that weight management is a long term strategy. Emphasis is placed on the importance of aiming for 10kg weight loss (or 10% if weight is <100kg) at 1 year.

Directly comparing LEAP Beep to other weight management interventions was challenging as no other identical interventions were found. However, as discussed earlier, Koreans Joo and Kim (2007) carried out a 12-week community-based weight management programme using text messaging. Each of the 433 patients was texted once weekly with health messages on diet, exercise and behaviour modification. A mean reduction in weight of 1.6 kg ($p < 0.001$) was found. LEAP Beep produced similar results (1.6kg weight loss' $p=0.013$).

The two main differences between the studies were that of responsiveness and intervention timing. LEAP Beep enabled feedback from the practitioner to the

participant. Joo and Kim (2007) sent one-way messages, thus reducing the time and effort burden on the practitioner as no response to the patient was necessary. Secondly, it must be borne in mind that LEAP Beep was used as an extension to the existing LEAP programme where participants had already lost an average of 4.1kg.

In the RCT carried out by Patrick et al. (2009) the intervention group ($n=33$) received one way text message support lost significantly ($p = 0.02$) more weight than the comparison group ($n=32$) (2.88 vs. 0.91 kg, 95% CI -0.34 to -3.60 kg) at four months. This study was conducted over a longer period than LEAP Beep and again, similarly to the study by Joo and Kim (2007) was used as the *initial* intervention for weight loss. Although the messages were one way only, (practitioner to patient) the intervention group participants chose the frequency and timing of the messages they received. Drawing out the actual contribution of the text messaging is challenging because the intervention group also received regular literature and phone calls.

The RCT by Haapala et al. (2009) studied 125 overweight adults that joined either an experimental group ($n=62$) to use a mobile phone based weight loss programme or to a control group ($n=63$) receiving no intervention. At three months the experimental group lost 4.5 ± 3.1 kg. This is more weight than that lost through LEAP Beep in the same time frame. However, it should be remembered that unlike LEAP Beep, participants in the study by Haapala and colleagues (2009) were not excluded for parallel attendance at other weight management groups, thus determining the true effect of text messaging would prove to be difficult.

In this study into the efficacy of LEAP, the control group gained 0.7 kg in the 12-week period after completion of the original LEAP programme (start 98.2 ± 15.4 kg; end

98.9 ±15.1 kg). The difference between the intervention and control groups was found to be significant ($p=0.006$).

Preventing or minimising weight regain following weight loss is particularly challenging. This study's findings are in line with research by Wing et al. (2006) who found that following successful weight loss, the majority (72%) of patients who were offered only minimal practitioner support (a quarterly newsletter) regained more than 2.3 kg over an 18 month period.

It is necessary to highlight that weight maintenance as well as weight loss are both successful outcomes following weight loss interventions. The figure below highlights the potential outcomes through a period of weight management. The natural course of weight change is for adults to gain approximately 1 kg each year. Therefore moderate weight loss or maintenance can be considered to be a successful outcome (WHO, 2000).

Successful Weight Management

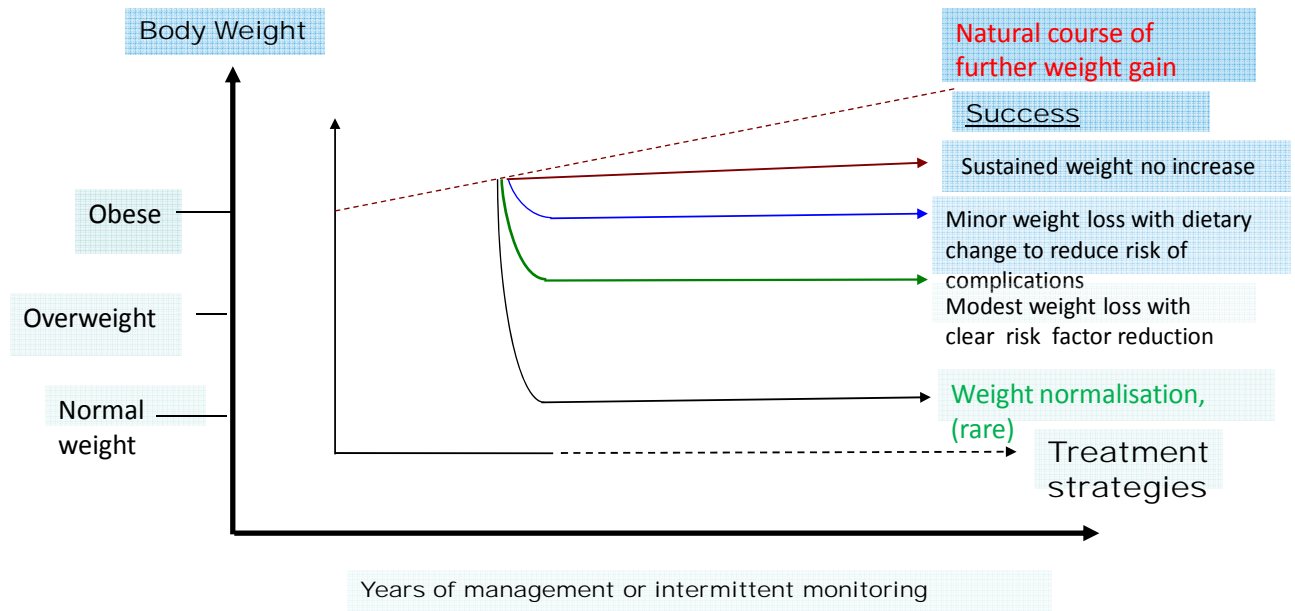


Figure 5. Potential weight outcomes following weight management intervention (WHO, 2000).

4.2.2 Waist circumference

NICE recommends measuring waist circumference in people with a BMI less than 35 kg/m² to assess health risks (NICE, 2006). Measuring waist circumference in people with BMI over 35 kg/m² does not provide further risk information but is often used as a secondary marker of weight loss (SIGN, 2010). Visceral intra-abdominal adiposity is the best predictor of the development of undesirable conditions related to excess body fat (WHO, 1997). Waist circumference measurements can be used to help establish the risk of further co-morbidities (Table 13.) Lean, Han and Seidell (1998) found that increased waist circumference was associated with an excess burden of disease including reduced ability to perform activities of daily living and increased diabetes and CVD risk.

A waist circumference $\geq 80\text{cm}$ for females and $\geq 94\text{cm}$ for males signifies an increased risk.

Table 13. Determination of risk status from waist circumference

	Low	High	Very high risk
Men	$<94\text{cm}$	$\geq 94 - 102\text{cm}$	$\geq 102\text{cm}$
Women	$<80\text{cm}$	$\geq 80\text{cm}$	$\geq 88\text{cm}$

NICE (2006)

LEAP Beep yielded a significant ($p=0.0005$) difference in waist circumference between control and intervention groups (-2.2cm vs. $+1.5\text{cm}$). LEAP Beep has therefore proved to be a successful programme to further reduce waist loss. (Evaluation of the original LEAP programme has shown an average waist circumference loss of 5.7cm [Appendix 18]). Haapala and colleagues (2009) found waist circumference reduced in their text message intervention by 5.9cm between baseline ($97.6 \pm 10.5\text{cm}$) and three months ($91.7 \pm 10.4\text{cm}$). The control group serves as an example of minimal intervention. As discussed previously, Joo and Kim (2007) found mean reductions in waist circumference of 4.3 cm ($P < 0.001$) during their 12-week community-based weight management programme using text messaging. No control data was taken until 12 months so it was therefore not comparable with the control group who gained 1.5cm ($p=0.035$).

4.2.3 BMI

BMI is an index of weight for height that is commonly used to classify whether an adult is underweight, normal weight or overweight. It is defined as the weight in kilograms divided by the square of the height in metres (kg/m^2) (WHO, 1997).

NICE (2006) recommend using BMI to classify the degree of a patient's obesity (Table 14). A BMI of $\geq 25\text{kg/m}^2$ is classified as overweight. A BMI of $\geq 30\text{kg/m}^2$ is classified as obese. At baseline a mean BMI of $35.6 \pm 5.0 \text{ kg/m}^2$ was recorded in the intervention group and median BMI of $35.1 \pm 5.2 \text{ kg/m}^2$ in the control group. These BMI values are both classified as 'obese'.

Table 14. Classification of overweight and obesity

BMI (kg/m^2)	WHO Classification
<18.5	Underweight
18.5 – 24.9	Normal weight
25.0 – 29.9	Overweight
>30	Obese
≥ 40	Morbidly obese

(NICE, 2006)

When BMI is used alongside waist circumference, a clearer picture of health risks can be achieved. NICE has grouped together BMI and waist circumference to enable practitioners to identify a patient's health risk and discuss this with them (Table 15). BMI gives an indication of the likelihood of development of co-morbidities such as diabetes, cardiovascular disease, hypertension, arthritis and some cancers (Campbell & Haslam, 2005). Increased mortality and higher disease incidence related to increased fat mass are seen most noticeably when BMI rises above 30 kg/m^2 (SIGN, 2010). Although, unfortunately there is not always a relationship between rising body mass, waist circumference and the patient's perceived health concern (Donaldson & McKenna, 2010a).

Table 15. Assessment of the risks from overweight and obesity

BMI (kg/m ²)	WHO Classification	Waist circumference		
		Low	High	Very High
25.0 – 29.9	Overweight	No increased risk	Increased risk	High risk
>30	Obese	Increased risk	High risk	Very high risk

(NICE, 2006)

Campbell and Haslam (2005) argue that BMI is a rather crude tool developed in Europe in the 1800's, originally used to examine *trends* in overweight. It was never explicitly designed to be used for concluding whether an individual is overweight. BMI reflects both fat and fat-free components of body mass; instead it gives a value based on total body weight. NICE (2006) comments:

- BMI may be less accurate in highly muscular people;
- for Asian adults, risk factors may be of concern at lower BMI;
- for older people, risk factors may become important at higher BMIs.

However, defining overweight and obesity by using BMI has become the gold standard (Campbell & Haslam, 2005).

In the study by Joo and Kim (2007) a mean reduction in BMI of 0.6 kg/m² ($p < 0.001$) was found. LEAP Beep also resulted in a significant difference of 1.5kg/m² ($p = 0.03$) in BMI between intervention and control groups (-0.6kg/m²; 0.7kg/m²). This difference may seem small but the health risks associated with any reduction in BMI are note worthy. In the intervention group one participant reduced their BMI

classification from 'morbidly obese' to 'obese'. The control group received minimal intervention and gained 0.7kg/m^2 (7.5% increase).

4.2.4 Anxiety and depression

Practitioners traditionally focus on measurable changes in health parameters such as weight and waist circumference to determine success of weight management interventions (Donaldson & McKenna, 2010b). In some interventions, patients' own views are largely overlooked; however, the patient is usually the best judge of their own wellbeing state (Fallowfield, 1993). Snaith (2003) states the importance of assessing the contribution of mood disorders, especially anxiety and depression to recognize the experience of suffering in the setting of medical practice. These combined facts make finding comparable data to compare with LEAP Beep challenging.

The prevalence of depression (10%) and overweight (65%) implies that the two conditions will co-occur (Stunkard, 2003). In this study the Hospital Anxiety and Depression Scale (HADS) was used to measure anxiety and depression. The HADS was designed to provide a simple yet reliable tool for use in medical practice. Despite the word 'hospital' in the title, the scale is valid when used in many community settings and primary care medical practice.

LEAP Beep produced improvements in anxiety and depression ($p=0.727$; $p=0.228$) between the groups. Although these results are not statistically significant, any improvements in mental wellbeing are desirable.

Elfhag and Rössner (2005) comment that depression is a common feature of obese patients accessing weight management treatment and that depression has been

linked with weight regain. McElroy, Kotwa, Malhotra, Nelson, Keck and Nemeroff (2004) offer that there is an overlap between obesity and mood disorders. Lower depression scores were a characteristic trait of people recovering from weight relapses compared to those that did not recover. It could therefore be proposed that a relative 'success' in weight management is where a reduction in depression is seen, as was in this study (Phelan, Hill, Lang, Dibello & Wing, 2003).

4.2.5 Quality of life

This study used the 'Impact of Weight on Quality of Life' tool. A validated self report measure of obesity specific quality of life with 31 items; physical function; self esteem; sexual life; public distress; work. The tool shows good internal consistency [0.90 – 0.96] (Koloktin, Crosby, Kosloski & Williams, 2001).

Measuring QOL is challenging because it is a broad term deficient in an exact definition. QOL is dependent on multiple features: family and friend support, ability to work and interest in one's occupations, accommodation appropriate to expectations and health and disabilities (Snaith, 2003). Less is known about health related QOL than many other parameters (Fontaine & Barofsky, 2001) However, it is known that obese people report impaired QOL and increasing impairments are related to increasing levels of obesity (Fontaine *et al.*, 2001).

This study has shown that 'LEAP Beep' produced improvements of 7.8 points ($p=0.134$) in QOL scores between intervention and control groups (-6.8; 1.0). Although these results are not statistically significant, Crosy, Koloktin and Williams (2004) suggest that an improvement of 7.7 to 12 points on IWQOL total score is considered to be a meaningful improvement. Evaluating QOL extends the scale of treatment

efficacy beyond weight loss and creates a valuable patient-centered viewpoint (Kushner *et al.*, 2000).

The RCT by Haapala *et al.* (2009) measured self efficacy in dieting, denoting trust in one's capability in achieving self-set goals for weight loss, reducing food intake, increasing physical activity and maintaining the weight loss with a scale ranging from 0 = 'not at all certain' to 9 = 'absolutely certain'. Haapala *et al.* (2009) found that the self efficacy score remained unchanged (7.0) between baseline and three months, despite changes in mean percentage weight loss of $5.3 \pm 3.5\text{kg}$. However, the authors found that the best predictors of weight loss at 12 months were percentage weight loss at 3 months ($p=0.0001$) and overall change in self-efficacy from baseline ($p=0.0001$). These results differ to that of LEAP Beep, where at three months, an improvement ($p=0.039$) in quality of life was seen, it is acknowledged that two entirely separate assessment tools were used. It is surprising that the Haapala *et al.* (2009) study did not find improvements in QOL measure, in the face of successful weight loss at 3 months. Differences in QOL measures can be partly explained by subjective the nature of the responses.

Assessing QOL benefits practitioners because it determines the patient's relationship with and overall impact on their condition. This provides further information beyond that collected by conventional medical and clinical measures and is important in helping understand the wide variation within individual responses to obesity (Fontaine *et al.*, 2001).

4.3 Changes in lifestyle variables

4.3.1 Steps walked

All adults should exercise more even if this does not lead to weight loss, because it has other health benefits, such as reduced risk of type 2 diabetes and cardiovascular disease (NICE, 2006). Many overweight and obese people report being active and being 'on their feet all the time'. However, overestimation of exercise in such population group is documented (Litchman et al. 1992).

Walking is one of the most frequent aspects of physical exercise reported by weight management study participants and is linked with less time spent on sedentary activities such as television watching (Wing & Hill, 2001). Increasing daily pedometer steps is a characteristic found in successful weight maintainers (Leser, Yanovski & Yanovski, 2002). In weight management programmes including pedometers the average daily step-count increases varied from around 2,000 steps per day to more than 4,000 steps per day (Richardson, Newton, Abraham, Sen, Jimbo & Swartz, 2008).

The LEAP Beep group increased their mean steps walked by 16.4% ($p=0.055$) from the beginning of the intervention compared to the end of the 12 week study (Table 7). This represents an increase of 1194 steps per person each day. Tudor-Locke and Bassett (2004) propose indices to classify step counts with physical activity levels in adults (Table 16). Using these indices, although the intervention group's average steps at the beginning of the study (6066 ± 2290 steps) increased by the end of the study (7260 ± 3258 steps) they are still classified as a 'sedentary' activity level.

However, the pedometer usage inspired some intervention group members (Appendix 19) to seek out local and national walks to increase their daily step count.

Table 16. Daily step counts and their corresponding activity level

Daily steps	Description	Activity Level
Less than 5000	Sedentary job	Sedentary
5000-7499	Daily activity without sports, exercise or voluntary activity	Low active
7500-9999	Includes some volitional activities (and/or elevated occupational activity demands)	Somewhat active
Equal or more than 10000	-	Active
Equal or more than 15000	-	Highly active

(Tudor-Locke and Bassett, 2004)

However, it must be remembered that the intervention group were able to relate their step count from either weekend or any of the weekday in which they wore their pedometer. It could have been possible for patients to choose a day that yielded a high step reading and send the value as being representative of their weekday or weekend steps. Once a step target was reached, a new target was set for achievement. During the collection of study end results, one intervention participant admitted she would often text her lowest readings to ensure she would not be set a higher target to achieve. It would be difficult to determine how this deliberate underreporting affected the data. To optimise the accuracy of the pedometer readings, patient's with a flap / apron of skin overhanging their waistband were advised to consider wearing the instrument midway along the waistband between their hips and spine at the back. This advice was given in an initial discussion about pedometers to the intervention group to ensure no participant felt singled out.

4.3.2 Fruit and vegetable intake

Haapala et al. (2009) found that at three months 83% of those completing the 12-month study reported increasing the portions of vegetables consumed (17 %). However, the baseline consumption of vegetables is unknown. In comparison, LEAP Beep participants showed less of an increase in their mean fruit and vegetable intake; 5.4% (5.3 ± 1.2 portions; 5.6 ± 1.4 portions; $p=0.249$).

At baseline and study end, 'LEAP Beep' participants claimed to consumed fruit *and* vegetables in excess of the current UK recommendations (five portions of fruit and vegetables each day) (WHO, 2003). In the UK, currently only 25% of men and 29% of women consume the recommended five or more portions of fruit and vegetables daily (The Health and Social Care Information Centre, 2008). This finding was surprising and poses the question of accuracy of determining portion size in the intervention group, despite spending a considerable amount of time discussion this topic during the initial LEAP group.

4.3.3 Breakfast consumption

Elfhag and Rössner (2005) profiled the 'successful weight maintainer' and highlighted the importance of a regular meal rhythm and always include breakfast. Very few studies have examined the direct effects of breakfast on obesity. However, Schlundt, Hill, Sbrocco, Pope-Cordle & Sharp (1992) randomised 'breakfast skippers to either a 1200kcal diet that included breakfast or a 1200kcal diet that excluded breakfast (i.e. two meals a day). They found mean weight loss of 7.7 ± 3.3 kg in the breakfast containing diet and a loss of 6.0 ± 3.9 kg in the breakfast skipped diet.

Consuming breakfast, especially in the case of 'skippers' could be beneficial for weight loss.

LEAP Beep participants' reported breakfast consumption was very high at baseline; only one participant did not eat breakfast every day. Text message data revealed he skipped breakfast 58.3% of the time ($n=14$), subsequently he gained 2.5% (3.0kg) during the intervention. Eating breakfast can lead to a reduction in total fat intake and eating unplanned, impulsive snacks that can be high in calories and fat (Schlundt, et al. 1992).

4.4 Relationships between health and lifestyle variables

The only significant correlation found between the three lifestyle variables and the six health variables was a negative correlation between the number of steps walked and depression score ($r=-0.671$) ($p=0.003$). Determining whether depression reduces obesity or obesity reduces depression is a source of interest in literature. It has been proposed that exercise is as effective as social contact for depressed elderly patients (McNeil, LeBlanc & Joyner, 1991). Blumenthal, Babyak and Moore (1999) found that exercise was as effective as antidepressants.

A stronger relationship was expected between steps walked and either body mass loss or BMI. However, discussion with the intervention group during final measurements produced some interesting albeit anecdotal findings. For two of the intervention group ($n=17$) their weekday vs. weekend steps varied considerably. One participant worked in a factory during the week and would regularly achieve >11000 steps daily whilst at work but his weekend steps were much lower (<5000). He gained 2.5% (3.0kg) during the intervention. Sustained high levels of daily steps will

cease to challenge the body to the same extent. It could be proposed that a degree of complacency over high weekday steps led to a fall in weekend steps and subsequently weight gain. In the future, participants in similar circumstances should be advised on activities that can be incorporated into everyday living, such as brisk walking, gardening or cycling (NICE, 2006).

4.5 Attrition differences between the groups

The intervention group attended significantly ($p=0.0005$) more appointments than the control group. One of the aims of the intervention was to determine how the text messaging would affect attendance at optional weight checks and subsequently attrition. The study showed that maintaining regular contact with participants encourages better attendance at weight checks. Whether regular attendance promotes weight management or simply whether successful weight losers attend because they want a Dietician to greet them with a congratulatory response is hard to determine. Regardless, the NWCR showed that regular monitoring of weight is a characteristic common to successful weight losers and maintainers so any reason that attracts patients for weight monitoring is beneficial (Wing & Hill, 2001).

4.6 Text messaging

A sample of the practitioner to patient dialogue is detailed in Appendix 20.

4.6.1 Frequency and confidentiality of messages

A high number of text messages were received from the intervention group. A maximum of 24 messages per participant could be sent. Mean messages sent by

participants was high; 23 ± 1.7 messages. Missed messages were reportedly due to illness, being abroad on holiday and lack of credit for mobile telephone. Although participants were instructed to only send their coded data e.g. 5549 fv3 bfn (and telephone the researcher with any other comments or questions) an additional five messages were received that contained information other than that requested, including:

- 'Penny has kennel cough and must be kept away from other dogs' (one participant explaining she has a low step count because her pet dog was poorly) [Appendix 21]
- 'the strap on my pedometer has broken, can I have a new 1 please?'
- 'sorry no data this weekend I have been ill'

In all of these the cases the patient was telephoned to resolve the issue and reminded to only text their coded information to optimise their confidentiality.

4.6.2 Immediacy of responses

Haapala et al. (2009) asked participants at 3 months to rate the four most useful features of the programme. Participants reported: the use of mobile phones and the Internet (93 % agreement), programme was free of charge (93 %), regular reporting of weight (91 %) and immediate feedback (90 %). It is unknown exactly how immediate 'immediate' referred to in this study. From the results from Haapala et al. (2009) it seems that the immediacy of response is an important aspect in a text messaging programme.

All LEAP Beep participants' messages were responded to within a maximum of 1 working day. A participant desiring immediate feedback is reliant on the practitioner

being available to provide the feedback and there is the potential for unrealistic expectations of feedback. In this study the researcher had access to a Blackberry which enabled out of hours feedback to the intervention group. It is acknowledged that few practitioners would be willing to provide support to patients during the evenings and weekends on a regular basis – unfortunately these are the times when patients desire support the most.

Gerber et al. (2009) discuss the advantages to using text messaging to promote healthy behaviours. There is a high distribution of mobile telephones among people, across income and ethnic groups. Mobile phones are popular, portable and convenient. There is much potential to personalise information and deliver it quickly. Gerber et al. (2009) comments that text messaging takes advantage of ‘push’ technology; data is transmitted to a user without them necessarily making the request. In comparison, other technology-based interventions often entail logging on to an Internet site or calling a telephone number and may be affected by poor reception and can be disruptive. Text messages are acceptable due to the ability to read messages discretely and the speed of sending/receiving messages (Gerber et al. 2009). However, it is acknowledged that some people such as the elderly, low literacy skills or those with a lower disposable income may not have access to a or desire to use a mobile telephone.

4.7 Patient satisfaction

Assessing the successfulness of an intervention from a participant centred viewpoint is important (Aharony & Strasser, 2003). Surveys were returned by 14 (82%) of the intervention group, this therefore represents a potentially biased group. The multiple choice section shows a very high overall satisfaction with messages sent from the researcher and with the programme overall. The additional comments section

provided an insight into the usefulness of the programme from the patient's perspective. LEAP Beep helped participants incorporate physical activity into daily life. Many participants comments that the programme had helped them to main their weight loss and provided goal to work towards. The programme was regarded as a 'way of life' rather than a 'diet'.

4.8 Study Limitations

The results from this study can be used to help inform future practice but there are many limitations that should be taken into consideration

4.8.1 Study design

This controlled study included a retrospective analysis of previously collected longitudinal data from participants in previous LEAP groups. Retrospective measurements were necessary due to the limited time frame of four months for data collection and prevented withdrawal of service. Retrospective studies are more prone to bias and confounding.

4.8.2 Sampling error

A random sample of the population was not used in this study; instead, participants already under the care of LNDS were sampled. This caused potential sampling errors, especially due to the low sample sizes (partly due to limited timeframes) used in the intervention ($n=17$) and control group ($n=17$). As commonly seen in research involving interventions, the problem of self-selection into (or out of) the study influences the degree to which the results can be generalised and has consequences

for dissemination (Heron & Smyth, 2010). Thus making extrapolation to the general population challenging.

4.8.3 Data Collection

The researcher was reliant on accurate lifestyle data (steps, fruit and vegetable intake and breakfast consumption) being sent from the participant. Lissner et al. (2000) has documented the potential for inaccuracies in self reporting, especially in the overweight and obese. All participants were instructed in the most accurate positioning of the pedometer and given manufacturers instruction booklets. There is potential for inaccurate fruit and vegetable portion measurement. The study showed that mean fruit and vegetable intake was already in excess of UK recommendations at the pre intervention stage (pre intervention; 5.3 ± 1.2 portions) the accuracy of this data is queried.

4.8.4 Confounding factors

The study outcomes may be affected by unconnected variables that can confound results and negatively affect internal validity. The participants that opted in to the intervention group may have already been more motivated to make lifestyle change compared to the control group, this also presents some selection bias. Other sources of confounding were degree of social support, mobility levels, gender and length of time being overweight or obese. The effects of these were not accounted for in study outcomes. Low sample numbers made it difficult to show significant results for some variables. Comparison of body mass differences between this and other studies was difficult due to wide variety of interventions, settings and whether or not the texting

intervention was the primary method of weight loss or an addition after a weight management programme, as in the case of LEAP Beep.

4.9 Recommendations

Any future plans to consider this type of remote support for health behaviours should consider some recommendations. Outlining timescales for sending and receiving data would ensure both patient and practitioner have realistic expectations about frequency of contact. Practitioners should emphasise that participants can text their data at *any time* of the day. This opens up potential for more accurate and convenient reporting of variables and may better suit some individuals (such as shift workers) because the participant does not need to wait until morning to send data. The practitioner must ensure the mobile phone or similar device is set to silent during periods where no correspondence is desired. It would be useful to inquire whether the participant would be travelling out with the UK during the intervention period; this would limit expensive overseas messages for both parties and may account for missed messages.

4.10 Areas for future research

Future evaluation of LEAP Beep and similar initiatives should involve larger sample numbers for a longer period of time, at least 6 months. Secondly, a comparison to identify whether a one way messaging system (practitioner - patient) thus eliminating the burden of responsive texts would yield similar weight loss results. Responding to LEAP Beep participants only took around 1 minute each day, (90 minutes each week) but a larger group number would require more time for response and weight loss benefits may be independent of the practitioner feedback. Further improvements to automation whilst maintaining individual support are necessary to ease practitioner

burden. Whether full automation would 'lack the personal touch' necessary would need to be investigated. Additional measures to monitor co-morbidity risk (blood sugars and blood pressure) would prove valuable.

4.11 Professional Implications

Providing further dietetic contact after an initial weight loss intervention is effective and yields a desirable weight outcome. Providing that contact through text messaging reduces staff time involved in playing 'telephone tag' or driving to locations to support patients. National obesity guidance stipulates follow up contact with weight management patients is necessary; dietetic services should consider the advantages to both parties of offering continued support via text messaging.

4.12 Conclusions

This study has indicated that LEAP Beep was acceptable to patients and successful in promoting reduction of body mass, waist circumference and BMI. Improvements were also seen in depression and quality of life measures. LEAP Beep demonstrated early efficacy for a responsive text messaging system to promote healthy behaviours on a frequent basis. This study is strengthened because it was carried out in a real practice setting and reflects normal clinical practice. The intervention was delivered by a Dietitian within a normal working environment and no incentives were given to participants.

Offering patients the opportunity to send and receive data around diet and exercise via mobile phone at their convenience opens up increasing possibilities for patient to practitioner support. Patients can send their data at a time convenient to them with the added bonus of practitioner feedback on their behaviours. Text messaging offers

an innovative and convenient mode of brief information exchange with patients involved in weight management programmes.

5.0 - References

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LEAP

Lifestyle, Eating and Activity Programme

ACTIVE together
HINCKLEY AND BOSWORTH



....helping you to eat smart and become more active!

Information Sheet

What is LEAP?

A **free** NHS weight management group with healthy eating and fun sports activities run by a Dietitian and a local exercise instructor. Each week there is a healthy eating topic to focus on and some group exercise. There are also weekly weigh-ins once the 12 week course finishes.

The aim is to lose weight sensibly and gradually and keep it off by learning about eating well and by being more active. Patients learn the skills they need to help them manage their weight on a long term basis. Daytime and evening courses are delivered. Any patient with a county GP can be referred to the programme. You need to have a BMI over 30kg/m² or over 28 kg/m² with other conditions such as high cholesterol, high blood pressure or diabetes. Your GP practice can measure your BMI.

Assessment appointment (usually 4 weeks prior to starting course)

- 60 minute assessment appointment with Dietitian
- Directions for the assessment will be sent with appointment time
- You will be asked if you can be weighed and have your waist measured
- We will talk about the kinds of foods you eat
- Together with the Dietitian, you will make initial goals to aim for

LEAP course

- One session each week for 12 consecutive weeks
- Small group size – ~ 15 people (male and female)
- Weighing is optional and done away from the other group members
- Each session comprises 90 mins nutrition and 60 mins exercise (might consist of walking, gym session, simple circuit, yoga, tai chi, street dance or Pilates)
- Discuss different healthy eating topics such as fats, sugars, label reading, comfort eating and snacks
- Bring something to drink and comfy clothes and soft shoes (ideally trainers)

After the course

- Regular follow up with the Dietitian
- Free regular weight checks to promote weight maintenance

How to join a course

- **ASK YOUR GP OR PRACTICE NURSE TO REFER YOU TO THE DIETITIAN AND WE WILL CONTACT YOU WITH THE DETAILS**

Leicestershire, Northamptonshire & Rutland Research Ethics Committee 1

1 Standard Court
Park Row
Nottingham
NG1 6GN

Telephone: 0115 8839428
Facsimile: 0115 9123300

19 May 2010

Miss Eleanor Donaldson

Dear Miss Donaldson

Study Title: Text messaging to improve weight management over 12 weeks in overweight Leicestershire adults.
REC reference number: 10/H0406/37
Protocol number: 1

The Research Ethics Committee reviewed the above application at the meeting held on 07 May 2010. Thank you for attending to discuss the study.

Ethical opinion

In discussion, the Committee queried the following issues:

1. The Committee requested clarification of the study numbers and how the comparison arm will be managed. You explained that data for the comparison arm has already been collected as part of service evaluation. Patients who have been through standard care now have three month data available. The researcher has access to data on more than 20 standard care patients but thought that it would help the analysis if the numbers were kept equal. There is not enough data to age and sex match the groups but they will be the same ratio of male and female patients. There have been about 60 patients who have been through the program but less who completed the HADs and QoL measures. The HADs and QoL are completed at the beginning of the program routinely but will also be done at the end for study.
2. The Committee asked how the text message feedback will be managed. You explained that the texts are not intended for open questions. Closed questions on a data set will be used. If a participant needs more general advice they will be able to telephone for advice.
3. The Committee asked how the personalised targets will be set. You explained that there is a national stepometer program. The average data for three days will be taken and used to calculate targets, these include increasing the number of steps taken by a 1000 or achieving a target of five a day fruit and vegetable intake.
4. The Committee asked how much the texts messages are likely to cost participants and if expenses can be claimed. You explained that there is no provision to pay for the texts. However, you have spoken to some patients and as there are only two texts that need to be sent each week they thought that it was acceptable.
5. The Committee asked whether the content of the text messages will be standardised.

You explained that they have a template on an Excel sheet. The person sending the text messages will just lift and copy from the template. When a reply is received there are three standard responses depending on whether the targets have been achieved. If the participant needs more advice then they will contact the researcher or their dietician.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research (“R&D approval”) should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

The information sheet should be checked for typographical errors. For example in table 2 "shoes" should read "shows". A copy of the corrected document, with updated version number and date, should be submitted for information.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>	
Covering Letter		21 April 2010	
REC application	44210/114918/1/442	23 April 2010	

Protocol	1	20 April 2010	
Letter from Sponsor		24 April 2010	
Letter from Statistician		23 April 2010	
Investigator CV			
CV - Eleanor Donaldson		21 April 2010	
Participant Instruction Booklet	1	15 April 2010	
Participant Information Sheet	2	22 April 2010	
Participant Consent Form	2	22 April 2010	
Evidence of insurance or indemnity		01 August 2009	
Questionnaire: HAD & IQOL tools	1	20 April 2010	
Letter to General Practitioner	1	13 April 2010	
Referral inclusion/exclusion criteria	1	20 April 2010	
LEAP Information Sheet	1	13 April 2010	
Sample Health tips	1	24 February 2010	
Patient intervention pathway	1	13 April 2010	
Sample researcher - patient dialogue	1	15 April 2010	
Referral form	1	20 April 2010	
Reference List	1	14 April 2010	

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- ☐ Notifying substantial amendments
- ☐ Adding new sites and investigators
- ☐ Progress and safety reports
- ☐ Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

With the Committee's best wishes for the success of this project

Yours sincerely

Dr Carl Edwards
Chair

Email: jeannie.mckie@nottspct.nhs.uk

*Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments
"After ethical review – guidance for researchers" SL-AR2 for other studie*

Copy to: Prof Sarah Andrew

R&D office for NHS care organisation at lead site – LNR CLRN



Leicestershire County and Rutland

Leicester, Leicestershire & Rutland Primary Care Research Office
C/o Leicestershire, Northamptonshire and Rutland
Comprehensive Local Research Network
Second Floor, Marriott Ward
Victoria Building
Leicester Royal Infirmary
Leicester, LE1 5WW

Miss Eleanor Donaldson
Senior Public Health Dietician
Leicestershire Nutrition and Dietetic Service
Charnwood Mill
Sileby Road
Barrow upon Soar
Leicestershire
LE12

17th June 2010

R&D Ref: LCR290410
REC Ref: 10/H0406/37

Dear Eleanor

I am pleased to confirm that **NHS Leicestershire County and Rutland** has reviewed your research study titled Text Messaging to Improve Weight Management over 12 Weeks in Overweight Leicestershire Adults and gives approval for you to conduct this research within the Trust on the condition that the Trust suffers no costs as a result of this study being undertaken. Your research has been entered onto the Trust's Research Database.

Please reply to this letter confirming the expected start date and duration of the study. As part of the Research Governance Framework it is important that the Trust is notified as to the outcome of your research and as such we will request feedback once the research has finished along with details of dissemination of your findings. We may also request brief updates of your progress from time to time, dependent on duration of the study. Similarly, if at anytime details relating to the research project or research team change, the R&D department must be informed.

If you have any further questions regarding this or other research you may wish to undertake in the Trust please feel free to contact me again. The Trust wishes you success with your research.

Yours sincerely

Clare O'Neill
RM&G Manager – Primary Care

Tel: 0116 258 7651
Email: clare.oneill@uhl-tr.nhs.uk

CC: Julian Mallinson – Consultant in Public Health NHS Leicestershire County & Rutland



Participant Information Sheet

A text message based weight management

intervention

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?

We know that after finishing a weight management group many people find it hard to keep up their levels of motivation. In this study, we can send you two motivating messages each week to remind you of some healthy lifestyle changes. You can tell us how you are getting on with your goals and we can send you some personalised advice in return.

Why have I been chosen?

You are eligible to participate in this study because you have completed Leicestershire Nutrition and Dietetic Service's LEAP group (Lifestyle, Eating and Activity Programme).

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect you in any way.

What will happen to me if I take part?

Each participant will be provided with a pedometer (step counter) for the duration of the study. Each week for a three month period you will be sent two text messages. The message will contain a health tip and we will ask you to send us (by text message) some information back about three different lifestyle behaviours:

1. Number of steps walked on the pedometer
2. Number of fruit and vegetable portions eaten
3. Whether you ate breakfast

Based on what you send us, we will send you a message back to encourage you and give you some more ideas about having a healthy lifestyle. Further information will be provided in a Participant Instruction Book.

What if I lose ability to consent during the study?

You will be withdrawn from the study, your data kept, and no further data taken.

What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks foreseen in taking part in the study.

What are the possible benefits of taking part?

This study aims to improve future treatment of weight management however it may not directly benefit you.

What if something goes wrong?

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, please contact Leicestershire Patient Advice Liaison Service, NHS Leicestershire County & Rutland, Loughborough Hospital, Epinal Way, Loughborough, LE11 5JY, 01509 664444 or pals@lcr.nhs.uk

Will my taking part in the study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential so that only the researcher carrying out the research will have access to such information.

What if I am already taking part in another medical study?

Talk to the researcher for advice.

What will happen to the results of the research study?

The results will be written up into a dissertation for my final project of my MSc. Individuals who participate will not be identified in any subsequent report or publication.

Who is organising and funding the research?

The researcher, the Centre for Exercise & Nutrition Science, Chester University and Leicestershire Nutrition and Dietetic Service.

Who may I contact for further information?

If you would like more information about the research before you decide whether or not you would be willing to take part, please contact:

Eleanor Donaldson, Senior Public Health Dietitian, Leicestershire Nutrition and Dietetic Service, Charnwood Mill, Sileby Rd, Barrow Upon Soar, LE12 8LR. Telephone: 01509 410 399 (Monday-Friday 9am-5pm).

Thank you for your interest in this research

**Title of Project: A text message based weight****Management intervention****Name of Researcher: Eleanor Donaldson**

Please initial box

1. I confirm that I have read and understand the information sheet dated 22/04/10 version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that my research data may be looked at by individuals from Leicestershire Nutrition and Dietetic Service, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my research data. ☐
4. I agree to my GP being informed of my participation in the study ☐
5. I agree to take part in the above study. ☐

Name of Patient

Date

Signature

Name of Person taking consent
(if different from researcher)

Date

Signature

Researcher

Date

Signature

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes

PARTICIPANT INSTRUCTION BOOKLET

A text message based weight management intervention

Researcher: Eleanor Donaldson, Senior Public Health Dietitian, Leicestershire Nutrition and Dietetic Service

Thank you for agreeing to take part in this MSc research project.

Introduction

The purpose of the study is to find out whether using text messaging to make contact with LEAP (Lifestyle, Eating and Activity programme) participants will help weight loss or weight maintenance over three months. We would like you to send us twice weekly text messages for a 3 month period with information about your lifestyle habits.

We will work with you to set a target for the three lifestyle habits below:

1. Number of steps walked each day (Each person will be lent a pedometer [step counter] for the duration of the study)
2. Portions of fruit and vegetables eaten each day
3. Eating breakfast each day

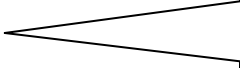
During this study, you can still attend the optional regular weight checks, phone the Dietitian and take part in any other LEAP group activities.

The information we send to you

We know that people's eating and exercise habits can be different during the week and at weekends, so we would like you to text us back with information from a weekday (Monday-Friday) and a weekend day (Saturday or Sunday). We will send you a brief text message on a Tuesday and a Friday to remind you to:

- Wear your pedometer for at least one weekday and a weekend day – you can choose which day
- Write down or remember how many portions of fruit and vegetables you have eaten that day
- Write down or remember whether you had breakfast or not

This is what one of the **reminder** text messages **we send you on a Tuesday and Friday** will look like.



"Remember to wear your step counter one weekday/weekend day this week and write down the fruit and vegetables you ate and whether you ate breakfast"

On a Monday and Thursday we will send you a message. The message will contain a health tip and a request for you to send us data on the number of steps you have walked, portions of fruit and vegetables you have eaten and whether you have eaten breakfast. This information will give us an idea of your lifestyle. The table below summarises which days we will send you text messages.

Day of the week	Type of message sent
Monday	<ul style="list-style-type: none"> • Request for weekend lifestyle habit data
Tuesday	<ul style="list-style-type: none"> • Reminder message to record weekday lifestyle habits
Wednesday	NO MESSAGE
Thursday	<ul style="list-style-type: none"> • Request for weekday lifestyle habit data
Friday	<ul style="list-style-type: none"> • Reminder message to record weekend lifestyle habits

This is what one of the **request** text messages **we send you** might look like.



The information you send to us

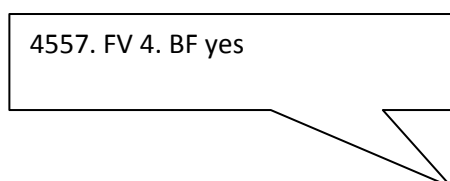
Each person will be lent a pedometer (step counter), we will work with you to make a step target for you to try and achieve each day. Everyone will have a target to eat 5 portions of fruit and vegetables each day. Everyone will have a target to eat breakfast each day. You will be asked to text us back with information about these three lifestyle habits. Table 2 below shows how your information needs to sent as a text message.

Lifestyle Habit	Quantity achieved	How to send back as a text message
<u>Steps walked</u> Example 1 Example 2	4557 steps 983 steps	04557 00983
<u>Number of fruit and vegetable portions</u> Example 1 Example 2	one banana, one glass fruit juice, 3 tablespoons sweet corn and one tablespoon raisins (= 4 fruit and vegetable portions) one orange and 3 tablespoons cauliflower (= 2 fruit and vegetable portions)	FV4 FV2
<u>Breakfast eating</u> Example 1 Example 2	Did eat breakfast (yes) Did not eat breakfast (no)	BF Yes BF No

When you send us back your text message you need to combine all three parts of the lifestyle information in one text message. We only need the information from one weekday and one weekend day. However, you can wear your step counter and monitor your fruit, vegetable and breakfast intake all week.

This is what one of the **response** text messages that **you send us back** might look like.

Figure 3. Sample response message you will send us

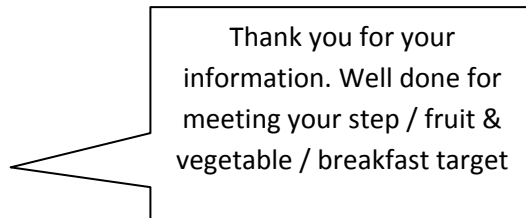


This would mean that the sender had walked 4557 steps, ate 4 fruit and vegetable portions and ate breakfast the previous day. You can send us back your message at anytime in the week that we send it to you.

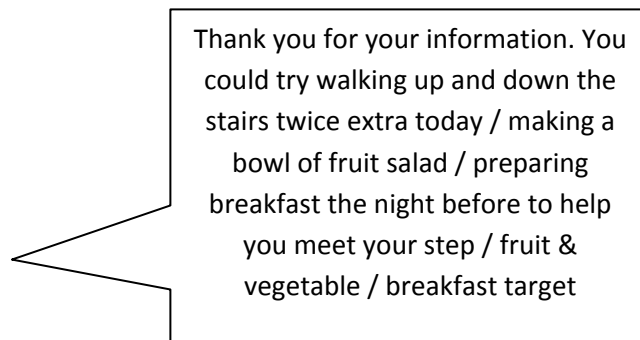
The information we send back to you

We will try to reply to your response text message on the day you send it, or the next working day. Based on what you send us, we will send you a personalised message back to encourage you and give you some more ideas about having a healthy lifestyle.

This is what one of the **feedback** text messages that **we send you** back might look like if you meet all of your targets (steps walked, fruit and vegetables and eating breakfast).



This is what one of the **feedback** text messages that **we send you** back might look like if you meet some of your targets.



If you need more advice from the Dietetics service, please phone our office instead of sending a text message with a question. This is the best way for us to support you. We will write to your GP to let them know you are taking part in this study. Please let us know if you do not want us to write to your GP.

At the end of the three months we will take the following measurements again:

- Weight
- Waist circumference
- Anxiety and depression
- Quality of life

Costs

Taking part in this study will involve sending two text messages each week to Leicestershire Nutrition and Dietetic Service. Unless your mobile phone package includes free text messages it will cost roughly 12-15p per text message.

What happens next?

For a further three months, we will continue to send you a health tip via text message once a week. You do not need to reply to this message. After this time, contact via text messaging will stop but you can still continue to attend the regular weight checks and any other LEAP activities.

Further Information

Talking and thinking about weight can sometimes be a distressing time. If you would like some more emotional support please contact the researcher, together you will be able to find the best person to discuss your needs with.

If you have any questions about the study, please contact:

Eleanor Donaldson,
Senior Public Health Dietitian,
Charnwood Mill,
Sileby Rd,
Barrow Upon Soar,
LE12 8LR.

01509 410 399

eleanor.donaldson@lnds.nhs.uk

Available Monday-Friday 9am – 5pm

This information booklet is for you to keep.



University of
Chester

Charnwood Mill
Sileby Rd
Barrow Upon Soar
Leicestershire
LE12 8LR
01509 410 399
www.lnds.nhs.uk

To:

Dear Dr

MSc Weight Management research project

'A text message based weight management intervention'

Patient Name:	D.O.B.	Our Ref:	NHS Number:
Address:			

Mrs X has agreed to take part in a MSc Weight Management research project.

Following your practice's referral to our service Mrs X attended the 12 week Lifestyle Eating and Activity Programme (LEAP) to promote weight loss. She is eligible to take part in the study because she completed the LEAP programme.

The purpose of the study is to investigate whether using text messaging will help patients to continue to lose weight or maintain their weight over the three month period after finishing LEAP.

After finishing a weight management group many people find it hard to keep up their levels of motivation. People are not always able to come back to the programme venue each week to discuss their progress. Letting people contact the Dietetic service by sending a text message might be a convenient way of keeping in touch.

In this study, we will send consenting patients two motivating messages each week to remind them of healthy lifestyle changes. They in turn let us know their progress with their goals and we send personalised advice in return. At the end of the study period, we will compare weight, waist circumference, anxiety and depression and quality of life scores with a LEAP group who received standard care (no text messages).

The Leicestershire Northamptonshire and Rutland Research Ethics Committee gave a favourable opinion on this research project on 19th May 2010. The enclosed Participant Information Sheet gives more details about the study. Please contact me, as the Principal Investigator, if you have any queries or would like more information about this study.

Yours sincerely

ELEANOR DONALDSON
Adult Weight Management Dietitian



Hospital Anxiety and Depression Scale (HADS)

Patients are asked to choose one response from the four given for each interview. They should give an immediate response and be dissuaded from thinking too long about their answers. The questions relating to anxiety are marked "A", and to depression "D". The score for each answer is given in the right column. Instruct the patient to answer how it currently describes their feelings.

A	I feel tense or 'wound up':	
	Most of the time	3
	A lot of the time	2
	From time to time, occasionally	1
	Not at all	0

D	I still enjoy the things I used to enjoy:	
	Definitely as much	0
	Not quite so much	1
	Only a little	2
	Hardly at all	3

A	I get a sort of frightened feeling as if something awful is about to happen:	
	Very definitely and quite badly	3
	Yes, but not too badly	2
	A little, but it doesn't worry me	1
	Not at all	0

D	I can laugh and see the funny side of things:	
	As much as I always could	0
	Not quite so much now	1
	Definitely not so much now	2
	Not at all	3

A	Worrying thoughts go through my mind:	
	A great deal of the time	3
	A lot of the time	2
	From time to time, but not too often	1
	Only occasionally	0

D	I feel cheerful:	
	Not at all	3
	Not often	2
	Sometimes	1
	Most of the time	0

A	I can sit at ease and feel relaxed:	
	Definitely	0
	Usually	1
	Not Often	2
	Not at all	3

D	I feel as if I am slowed down:	
	Nearly all the time	3
	Very often	2
	Sometimes	1
	Not at all	0

A	I get a sort of frightened feeling like 'butterflies' in the stomach:	
	Not at all	0
	Occasionally	1
	Quite Often	2
	Very Often	3

D	I have lost interest in my appearance:	
	Definitely	3
	I don't take as much care as I should	2
	I may not take quite as much care	1
	I take just as much care as ever	0

A	I feel restless as I have to be on the move:	
	Very much indeed	3
	Quite a lot	2
	Not very much	1
	Not at all	0

D	I look forward with enjoyment to things:	
	As much as I ever did	0
	Rather less than I used to	1
	Definitely less than I used to	2
	Hardly at all	3

A	I get sudden feelings of panic:	
	Very often indeed	3
	Quite often	2
	Not very often	1
	Not at all	0

D	I can enjoy a good book or radio or TV program:	
	Often	0
	Sometimes	1
	Not often	2
	Very seldom	3

	Scoring (add the As = Anxiety. Add the Ds = Depression). The norms below will give you an idea of the level of Anxiety and Depression.	
	0-7 = Normal	
	8-10 = Borderline abnormal	
	11-21 = Abnormal	

(Zigmond & Snaith, 1983).

Impact of Weight on Quality of Life Questionnaire: Lite Version (IWQOL-Lite)

Please answer the following statements by circling the number that best applies to you **in the past week**. Be as open as possible. There are no right or wrong answers.

<u>Physical Function</u>		ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
1.	Because of my weight I have trouble picking up objects.	5	4	3	2	1
2.	Because of my weight I have trouble tying my shoes.	5	4	3	2	1
3.	Because of my weight I have difficulty getting up from chairs.	5	4	3	2	1
4.	Because of my weight I have trouble using stairs.	5	4	3	2	1
5.	Because of my weight I have difficulty putting on or taking off my clothing.	5	4	3	2	1
6.	Because of my weight I have trouble with mobility.	5	4	3	2	1
7.	Because of my weight I have trouble crossing my legs.	5	4	3	2	1
8.	I feel short of breath with only mild exertion.	5	4	3	2	1
9.	I am troubled by painful or stiff joints.	5	4	3	2	1
10.	My ankles and lower legs are swollen at the end of the day.	5	4	3	2	1
11.	I am worried about my health.	5	4	3	2	1

<u>Self-esteem</u>		ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
1.	Because of my weight I am self-conscious.	5	4	3	2	1
2.	Because of my weight my self-esteem is not what it could be.	5	4	3	2	1
3.	Because of my weight I feel unsure of myself.	5	4	3	2	1
4.	Because of my weight I don't like myself.	5	4	3	2	1
5.	Because of my weight I am afraid of being rejected.	5	4	3	2	1
6.	Because of my weight I avoid looking in mirrors or seeing myself in photographs.	5	4	3	2	1
7.	Because of my weight I am embarrassed to be seen in public places.	5	4	3	2	1

<u>Sexual Life</u>		ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
1.	Because of my weight I do not enjoy sexual activity.	5	4	3	2	1
2.	Because of my weight I have little or no sexual desire.	5	4	3	2	1
3.	Because of my weight I have difficulty with sexual performance.	5	4	3	2	1
4.	Because of my weight I avoid sexual encounters whenever possible.	5	4	3	2	1
<u>Public Distress</u>		ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE
1.	Because of my weight I experience ridicule, teasing, or unwanted attention.	5	4	3	2	1
2.	Because of my weight, I worry about fitting into seats in public places (e.g.theaters, restaurants, cars, or airplanes)	5	4	3	2	1
3.	Because of my weight I worry about fitting through aisles or turnstiles.	5	4	3	2	1
4.	Because of my weight I worry about finding chairs that are strong enough to hold my weight.	5	4	3	2	1
5.	Because of my weight I experience discrimination by others.	5	4	3	2	1
<u>Work</u> (Note: For homemakers and retirees, answer with respect to your daily activities.)		ALWAYS TRUE	USUALLY TRUE	SOMETIMES TRUE	RARELY TRUE	NEVER TRUE

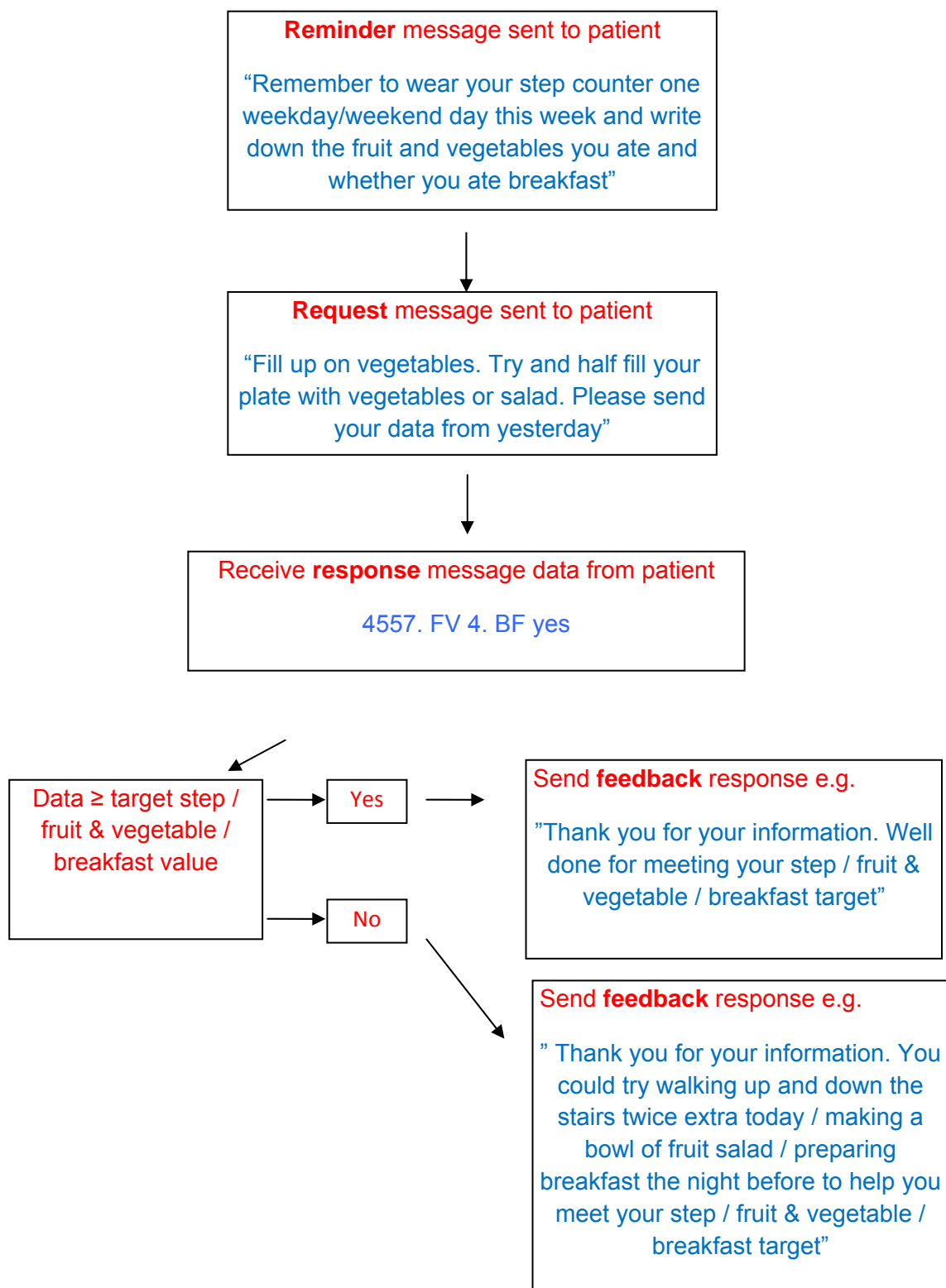
1.	Because of my weight I have trouble getting things accomplished or meeting my responsibilities.	5	4	3	2	1
2.	Because of my weight I am less productive than I could be.	5	4	3	2	1
3.	Because of my weight I don't receive appropriate raises, promotions or recognition at work.	5	4	3	2	1
4.	Because of my weight I am afraid to go on job interviews.	5	4	3	2	1

	Frequency of weight affecting quality of life				
Quality of Life component	Never	Rarely	Sometimes	Usually	Always
Physical function	11-16	17-27	28-38	39-49	50-55
Self esteem	7-10	11-17	18-24	25-31	32-35
Sex life	4-5	6-9	10-13	14-17	23-25
Public distress	5-7	8-12	13-17	18-22	23-35
Work and home life	4-5	6-9	10-13	14-17	18-20

(Koloktin et al. 2001)

Sample researcher to patient dialogue

Following an instruction session, subjects will be sent a text message with health tip and a prompt to send back their data. Figure 1 highlights the dialogue pathway between researcher and patient.



Introduction:

Body weight helps to determine their BMI, which is their weight relative to their height, and therefore to determine the prevalence of overweight and obese people in the population.

Equipment:

- Portable electronic weighing scale
- A stiff wooden board to place under the scales, if there is likely to be problems with uneven surfaces (such as dirt or mud floors or carpet)
- A generator, if electronic scales are being used and electricity is not available (check if scale can work with batteries)

Set up:

Make sure the scales are placed on a firm, flat surface.

Do not place the scales on:

- Carpet
- A sloping surface
- A rough, uneven surface

Follow the steps below to put electronic scales into operation:

1. Put the scale on a firm, flat surface.
2. Connect the adaptor to the main power line or generator.
3. Turn on the scale.
4. Switch the scale on and wait until the display shows 0.0.

Procedures

5. Ask the participant to remove their footwear (shoes, slippers, sandals, etc) and socks.
6. Ask the participant to step onto scale with one foot on each side of the scale.
7. Ask the participant to:
 - Stand still
 - Face forward
 - Place arms on the side and
 - Wait until asked to step off
8. Record the weight in kilograms on the participant's instrument. If the participant wants to know his/her weight in pounds, convert sby multiplying the measured weight by 2.2.

(World Health Organisation, 2008)

Appendix 12: World Health Organisation
standardised technique for measuring waist
circumference of adults.

Introduction:

Waist circumference measurements are also taken to provide additional information on overweight and obesity.

Privacy:

A private area is necessary for this measurement. This could be a separate room, or an area that has been screened off from other people.

Equipment:

- Constant tension tape
- Pen
- Chair or coat stand for participants to place their clothes

Set up:

This measurement should be taken without clothing, that is, directly over the skin. If this is not possible, the measurement may be taken over light clothing. It must not be taken over thick or bulky clothing. This type of clothing must be removed.

Procedure:

This measurement should be taken:

- At the end of a normal expiration
 - With the arms relaxed at the sides
 - At the midpoint between the lower margin of the last palpable rib and the top of the iliac crest (hip bone)
1. Standing to the side of the participant, locate the last palpable rib and the top of the hip bone. You may ask the participant to assist you in locating these points on their body.
 2. Ask the participant to wrap the tension tape around themselves and then position the tape at the midpoint of the last palpable rib and the top of the hip bone, making sure to wrap the tape over the same spot on the opposite side. (Check that the tape is horizontal across the back and front of the participant and as parallel with the floor as possible)
 3. Ask the participant to:
 - Stand with their feet together with weight evenly distributed
 - Across both feet;
 - Hold the arms in a relaxed position at the sides;
 - Breathe normally for a few breaths, then make a normal expiration.
 4. Measure waist circumference and read the measurement at the level of the tape to the nearest 0.1 cm, making sure to keep the measuring tape snug but not tight enough to cause compression of the skin.
 5. Record the measurement on the participant's Instrument. Measure only once and record.

(World Health Organisation, 2008)

Appendix 13: Samples of health tips sent to participants

	Step counts	Fruit and vegetable consumption	Breakfast consumption
1	Try stepping to your favourite song on the radio	Try making up a bowl of fruit salad to nibble	Try making breakfast the night before
2	Try stepping up and down bottom step of house or stairs	Veg sticks and tomato salsa is a good snack	Try having a wholegrain breakfast cereal
3	Try stepping during ad breaks on tv	150 ml fruit juices counts towards f+v (but only once a day)	Try a cereal bar for breakfast
4	Try stepping whilst waiting for kettle to boil	Homemade smoothies count towards f+v	2 slices fruit bread can be a tasty breakfast
5	Could walk up + down every aisle in supermarket	Baked beans and other pulses counts as f +v	Eggs make a good breakfast; boil, poach or scramble?
6	Park farther away from destination	Tomato based sauces for pasta dishes count as f + v	Add toppings to cereal e.g. tablespoon raisins or chop apricots
7	Avoid using stairs or lift for few days- walk more	Remember dried fruit can count towards 5 a day	Take breakfast with you; wrap up toast in foil and go!
8	Maybe try 10 minute walk after dinner for few days this week	Can add sliced fruit to toast or cereal	Bored of bread /cereal? Try potato scones, pancakes or crumpets!
9	Use farthest away toilet in the house / shops etc	Tinned fruit can count towards 5 a day	Try thinly spreading your toast with marmite, peanut butter or lemon curd?
10	Walk whilst you are chatting on the phone	Frozen f+v is just as good for you as fresh	Try whizzing a breakfast smoothie with a handful of breakfast cereal



Instructions - Patient satisfaction survey

A text message based intervention

It will help the researcher find out your opinions about the text messaging program

- It contains 12 multiple choice answers and one question where you can write extra comments on the program if you wish
- It should take you approximately 10 minutes to complete
- Most of the questions are asked as a statement, you should answer by placing one tick in the box that best describes how much you agree with the statement

For example:

- | | |
|----------------------------|-------------------------------------|
| Strongly agree | <input checked="" type="checkbox"/> |
| Agree | <input type="checkbox"/> |
| Neither agree nor disagree | <input type="checkbox"/> |
| Disagree | <input type="checkbox"/> |
| Strongly disagree | <input type="checkbox"/> |

- The final question gives you the opportunity to add any extra comments about the text messaging program
- The survey is anonymous, you do not have to give your name or any contact details
- Once you have finished the survey please place it in the envelope and either give it to the researcher (Eleanor Donaldson) or post it in the stamped addressed envelope
- Thank you for your time and your interest in this research

Patient satisfaction surveyA text message based intervention

1. I was given enough information about the text messaging programme before I took part

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

4. I was happy with how long the dietitian took to respond to my message

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

2. I found the text messaging programme easy to use

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

5. If I didn't meet my step target, I was happy with the tip I received to help me increase it

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

3. I was happy with how many times I was contacted via text message during the 12 week programme

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

6. If I didn't meet my fruit and vegetable target, I was happy with the tip I received to help me increase it

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

t target, I
red to

Strongly agree ☐

Agree ☐

Neither agree nor disagree ☐

Disagree ☐

Strongly disagree ☐

8. I felt that the text messaging programme has helped me to maintain or improve the amount of steps I walk each day

Strongly agree ☐

Agree ☐

Neither agree nor disagree ☐

Disagree ☐

Strongly disagree ☐

9. I felt that the text messaging programme has helped me to maintain or improve the amount of fruit and or vegetables I eat

Strongly agree ☐

Agree ☐

Neither agree nor disagree ☐

Disagree ☐

Strongly disagree ☐

10. I felt that the text messaging programme has helped me to maintain or improve how often I eat breakfast

Strongly agree ☐

Agree ☐

Neither agree nor disagree ☐

Disagree ☐

Strongly disagree ☐

11. I felt that the dietitian encouraged me to make positive lifestyle changes

Strongly agree ☐

Agree ☐

Neither agree nor disagree ☐

Disagree ☐

Strongly disagree ☐

12. Overall, I felt satisfied with the text messaging programme

Strongly agree ☐

Agree ☐

Neither agree nor disagree ☐

Disagree ☐

Strongly disagree ☐



write additional comments about the text messaging program

Thank you for taking the time to complete this questionnaire, your comments are very much appreciated. Please either return it directly to Eleanor Donaldson (researcher / Dietitian) or use the stamped addressed envelope to post it back within one week.

Appendix 15. No significant difference
between baseline health variables in
control and intervention groups

Independent Samples Test								
		Levene's Test for Equality of Variances		t-test for Equality of Means				
		F	Sig.	t	df	Sig. (2- tailed)	Mean Difference	Std. Error Difference
Baseline waist	Equal variances assumed	.002	.961	.293	32	.771*	1.235	4.210
	Equal variances not assumed			.293	31.996	.771*	1.235	4.210
Baseline quality of life	Equal variances assumed	3.177	.084	1.196	32	.241*	10.765	9.004
	Equal variances not assumed			1.196	24.681	.243*	10.765	9.004

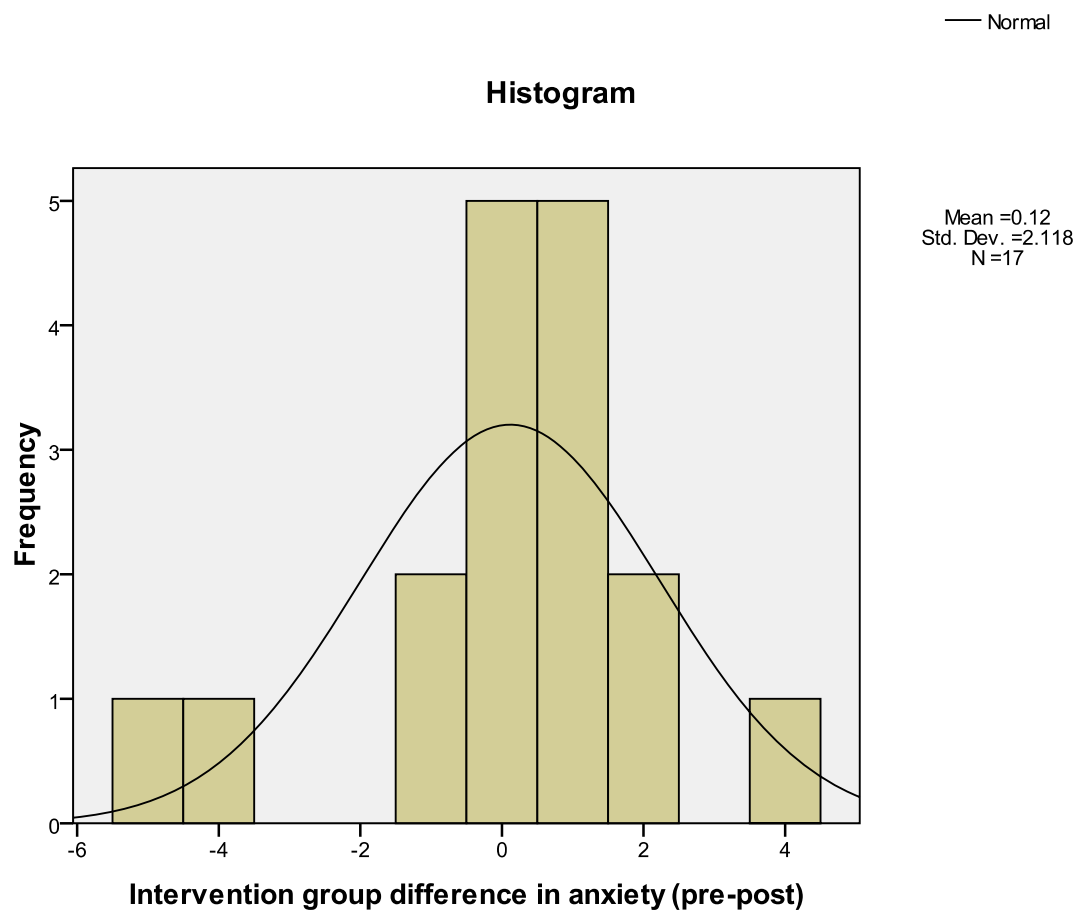
*No significant ($p > 0.05$) difference between baseline characteristics in the control and intervention groups

Test Statistics ^b					
	Baseline weight	Baseline Body Mass Index	Age	Baseline depression	Baseline anxiety
Mann-Whitney U	138.000	132.500	140.500	88.000	138.500
Wilcoxon W	291.000	285.500	293.500	241.000	291.500
Z	-.224	-.413	-.138	-1.961	-.207
Asymp. Sig. (2-tailed)	.823*	.679*	.890*	.050*	.836*
Exact Sig. [2*(1-tailed Sig.)]	.838 ^a	.683 ^a	.892 ^a	.053 ^a	.838 ^a
a. Not corrected for ties.					
b. Grouping Variable: group					

*No significant ($p > 0.05$) difference between baseline characteristics in the control and intervention groups

Tests of Normality						
	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Intervention group difference in anxiety (pre-post)	.243	17	.009	.884	17	.038
a. Lilliefors Significance Correction						

Although the Shapiro -Wilk statistic (Coakes & Steed, 2007) implies the data is not normally distributed, a histogram (below) shows the data does follow the bell shaped curve seen in normally distributed data (Field, 2009).



Appendix 17. Raw intervention group data for
pre (week 1) and post (week 12) weight, waist
circumference, QOL, anxiety and depression

Patient ID	Health Variable									
	weight 1	Weight 1 2	waist 1	waist 12	QOL 1	QOL 12	Anxiety 1	Anxiety 12	Depression 1	Depression 12
1	74.8	72.8	94	93	41	41	1	2	0	0
2	113.1	114.9	107	112	104	65	11	12	9	7
3	101.2	99.2	121	118	81	80	6	6	0	0
4	120.5	123.5	132	132	81	67	3	7	1	5
5	81.5	78.8	94	93	44	38	3	3	0	0
6	96.1	95.5	117	115	70	59	13	12	6	7
7	101.2	100.5	118	117	58	62	8	8	3	3
8	75.2	73.9	95	94	49	41	4	4	1	0
9	110.8	106.5	127	122	77	77	11	9	6	3
10	98.5	96.7	121	118	73	62	7	6	3	0
11	74.3	74.5	112	112	60	73	8	6	5	3
12	111.8	108.9	119	116	60	52	5	10	2	3
13	93.7	88.8	100	97	67	84	14	10	6	9
14	97.8	93.6	130	128	92	80	5	5	3	1
15	97.5	94.2	115	109	49	35	4	3	1	1
16	110.1	112.3	125	122	67	52	7	6	1	1
17	91.6	85.2	117	108	45	34	3	2	1	1

LNDS Adult Weight Management Groups Update

September 2010



LEAP Background

- 'Lifestyle Eating and Activity Programme'
- Nutrition from Leicestershire Nutrition and Dietetic Service
- Physical activity from Active Together
- Free 12 week course - 90 mins nutrition and 60 mins physical activity
- Post course – regular weight check and regular follow up support
-

Current Courses

- LEAP Hinckley (evening group) - 15 participants at St Francis Centre, Hinckley
- LEAP Coalville (evening group) - 17 participants at the Brass House, Coalville
- LEAP Wigston (daytime group) - 15 participants at Basset St Centre, Oadby & Wigston,

Table 1. LEAP anthropometric outcomes

	LEAP cohort 4 (Hinckley)	LEAP cohort 5 (Hinckley)	LEAP cohort 6 (Hinckley)	LEAP cohort 7 (Loughborough)
Course Dates	Jan - March 2010	Feb - May 2010	April - July 2010	June - August 2010
Average Weight loss (%)	3.3% (range 0 – 14.1)	5.1% (range 1.4 – 13.9)	4.6% (range 1.2 – 7.9)	2.3% (range 0 – 6.0)
Average Weight loss (kg)*	3.5kg (range 0 – 14.6)	5.5kg (range 1.5 – 19.4)	4.5kg (range 0 – 8.3)	2.7kg (range 0 – 6.3)
Average Waist circumference loss	5.6cm (range 0 – 12cm)	6.3cm (range 0 – 12cm)	5.2cm (range 0 – 12cm)	5.0cm (range 0 – 9cm)
Overall attendance	83%	88%	94%	84%

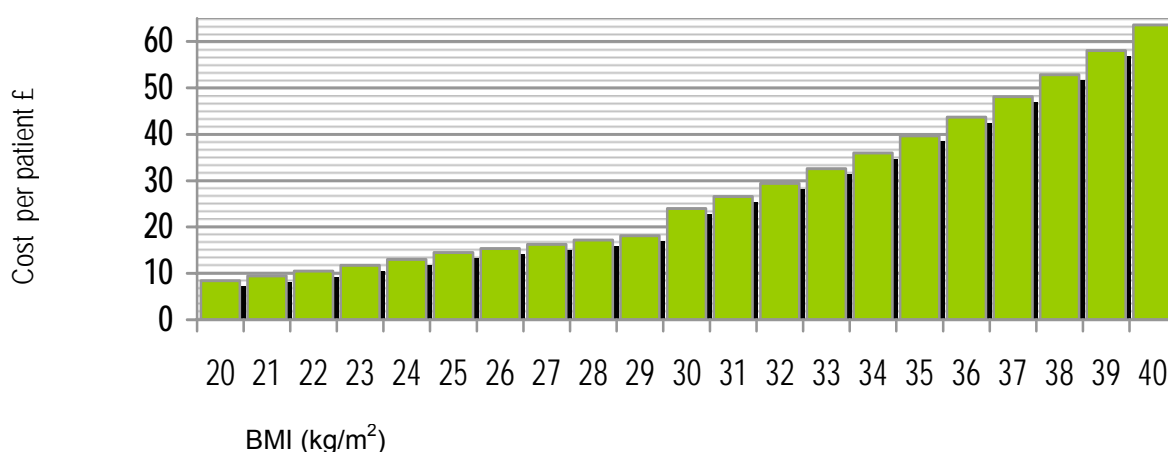
*NB Average of 3.3kg weight loss at 3 months in a fully evaluated evidence based weight loss programme (Br J Gen Pract 2008; 58: 548-554).

- ✓ LEAP yields statistically significant **weight** loss ($p < 0.001$) and **waist** loss ($p < 0.001$)
(Using Wilcoxon signed ranks tests and SPSS version 17.0)

Health Economics

Prevention of increases in BMI on prescribing costs (Figure 1) shows savings around weight management. These are best presented as 'cost avoidance' where the intervention would prevent the ongoing increases in costs with year on year increases in BMI. With no intervention to reduce body mass, the year on year increase in the ten most commonly prescribed medications has been established; the avoidance of this increase brings long term cost avoidance.

Figure 1. Cost savings associated with avoidance of increasing BMI



When weight gain is avoided so are the associated costs and burden on general practice such as increased use of general practice appointments, increased drug expenditure and increased costs associated with the development of obesity related disease.

What's hot?

LEAP 6 confidence to make healthy changes to diet increased from 56% before the course to 91% after LEAP

Participant comments:

- ✓ "Just wanted to say thank you for helping me and my family, for changing our lives!!!"
- ✓ "LEAP has helped me to realise that I wasn't eating as healthily as I thought I was. The support has been brilliant"
- ✓ "It has changed my life as I have gained confidence as I have lost weight, less pain from arthritis and I am a lot more active
- ✓ "I always grate the cheese so I use much less than before, I eat much less cereal than before, for snacks I usually have fruit or a few nuts instead of crisps and biscuits."

Most enjoyed nutrition sessions: comfort eating, food labels and the supermarket tours

Most enjoyed exercise sessions: frisbee and street dance

What's New?

- ✓ LEAP information now available for public and patients on the LNDS website, click [here](#) for details
- ✓ Previous group members attend first week of new groups to support and inspire new starters
- ✓ A supermarket tour is now included as part of each LEAP group
- ✓ LEAPers can opt in for text message reminders of weekly activities

LEAP 7 (Loughborough) Celebration

LEAP 7 finished their course on 31st August 2010 after a supermarket tour round Loughborough Tesco and celebrated their achievements with a red carpet presentation and goody bags

Long term follow up

- LEAPers continue to attend regular weight checks after current groups finish. Drop in time slots are available in the mornings, afternoons and evenings to meet patient demand.

Contacts

More information from eleanor.donaldson@lnds.nhs.uk or deborah.nelson@lnds.nhs.uk 01509 410 399

Appendix 19. 'LEAP Beep' participants wearing pedometers during the 12-week intervention period

Appendix 20. Sample researcher to patient
text message dialogue

From	Subject	Received	Size
Donaldson Eleanor Well done all targets met, keep up the good work :) <end> [SMS]- 16357 fV5 bfy	RE: [SMS]+ [SMS]-	Fri 20/08/2010 10:38	1 KB
Donaldson Eleanor 16357 fV5 bfy		Thu 19/08/2010 22:06	911 B
Donaldson Eleanor Please send your WEEKDAY data :) <end> [SMS]+	Re: [SMS]+ [SMS]+	Thu 19/08/2010 21:27	777 B
Donaldson Eleanor Well done all targets met, new step target = 6789 steps each day <end> [SMS]+4 13989 fV5 bfy	RE: [SMS]+ [SMS]+4	Tue 17/08/2010 15:43	1 KB
Donaldson Eleanor 13989 fV5 bfy		Mon 16/08/2010 21:50	911 B
Good morning, please send your WEEKEND data :) <end> [SMS]+	Re: [SMS]+ [SMS]+4	Mon 16/08/2010 10:12	1 KB
Donaldson Eleanor Well done you met all your targets, have a great weekend :) <end> [SMS]+4 6501fV5 bfy	RE: [SMS]+ [SMS]+4	Sat 14/08/2010 09:17	833 f
Donaldson Eleanor 6501fV5 bfy		Fri 13/08/2010 20:20	907 f
Donaldson Eleanor Please send your WEEKDAY data :) <end> [SMS]+	RE: [SMS]+ [SMS]+4	Fri 13/08/2010 11:09	1 KB
Donaldson Eleanor Well done you met all your targets!! <end> [SMS]+4 7246fV5 bfy	RE: [SMS]+ [SMS]+4	Tue 10/08/2010 15:40	1 KB
Donaldson Eleanor 7246fV5 bfy		Mon 09/08/2010 18:53	907 B
Donaldson Eleanor Please send your WEEKEND data :) <end> [SMS]+	RE: [SMS]+ [SMS]+4	Mon 09/08/2010 10:04	1 KB
Donaldson Eleanor Well done u met bf+f+v target. Little xtra stair walking today-almost @ step target <end> [SMS]+4 5120 fV5 bfy	Re: [SMS]+ [SMS]+4	Fri 06/08/2010 11:35	879 B
Donaldson Eleanor 5120 fV5 bfy		Thu 05/08/2010 17:28	909 B

Appendix 21. Examples of rogue text messages

